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Application Proof of



Vigonvita Life Sciences Co., Ltd. 蘇州旺山旺水生物醫藥股份有限公司

(a joint stock company incorporated in the People's Republic of China with limited liability)

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Vigonvita Life Sciences Co., Ltd.
蘇州旺山旺水生物醫藥股份有限公司
(a joint stock company incorporated in the People's Republic of China with limited liability)

[REDACTED]

Number of [REDACTED] in : [REDACTED] H Shares (subject to the the [REDACTED] [REDACTED])
Number of [REDACTED] : [REDACTED] H Shares (subject to reallocation)
Number of [REDACTED] : [REDACTED] H Shares (subject to reallocation and the [REDACTED])
Maximum [REDACTED] : HK\$[REDACTED] per H Share, plus brokerage of 1.0%, SFC transaction levy of 0.0027%, AFRC transaction levy of 0.00015% and Stock Exchange trading fee of 0.00565% (payable in full on application in Hong Kong dollars and subject to refund)
Nominal Value : RMB1.00 per H Share
[REDACTED] : [REDACTED]

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[REDACTED]

IMPORTANT

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

CONTENTS

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SUMMARY

*This summary aims to give you an overview of the information contained in this document and is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial information appearing elsewhere in this document. As this is a summary, it does not contain all the information that may be important to you and we urge you to read the entire document carefully before making your [REDACTED] decision. There are risks associated with any [REDACTED]. **In particular, we are a biotechnology company seeking a [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED].***

OVERVIEW

Founded in 2013, we are a fully-integrated biopharmaceutical company dedicated to the discovery, development and commercialization of innovative small molecule drugs. With mission to innovate for better health and quality of life, we strive to address the diverse and evolving patient needs in our strategically focused therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health. Over the past 12 years, we have not only established end-to-end capabilities spanning the entire industry value chain from research and clinical development to manufacturing and commercialization, but also developed a distinguished innovative pipeline of nine innovative assets, including three Core Products, VV116, LV232 and TPN171 each with first- or best-in-class potential.

VV116 is a RNA-dependent RNA polymerase (“**RdRp**”) inhibitor which has been approved for the treatment of COVID-19 in China and Uzbekistan under the trade names 民得維[®] and MINDVY[®], respectively, and is currently under Phase II/III clinical development for the treatment of respiratory syncytial virus (“**RSV**”) infection in China. LV232 is a potential first-in-class dual-target serotonin transporter (“**5-HTT**”)/5-hydroxytryptamine 3 (“**5-HT₃**”) receptor modulator current in preparation for a Phase II clinical trial for the treatment of depression. TPN171 is a potential best-in-class, highly potent and highly selective phosphodiesterase 5 (“**PDE5**”) inhibitor, which has been approved for the treatment of erectile dysfunction (“**ED**”) in Uzbekistan and is anticipating to obtain new drug application (“**NDA**”) approval for the same indication from the National Medical Products Administration of the PRC (“**NMPA**”).

THERE IS NO ASSURANCE THAT WE WILL ULTIMATELY BE ABLE TO DEVELOP AND MARKET OUR CORE PRODUCTS OR ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.

SUMMARY

The following chart shows our pipeline of innovative assets as of the Latest Practicable Date:

Pipeline Product	Target	Indications (Lines of Treatment) ⁶	Preclinical	IND-Enabling	Phase I	Phase II	Phase III	NDA	Commercial Rights ⁵	Upcoming Milestone
Viral Infection	VV116 (MINDVY® 民得維®)	Viral Polymerase	COVID-19					China	Joint Biotech ² Co-Owned with CAS ³	N/A
	VV261	Viral Polymerase	RSV					Uzbekistan	Global ⁴	To complete Phase II in Q2 2025
	VV207	Viral Polymerase	Severe Fever with Thrombocytopenia Syndrome Virus						Global	To initiate Phase II in 1H 2027
Neuropsychiatry	LV232	Confidential	Adenovirus						Global	To submit IND in 2H 2026
	TPN102	5-HTT and 5-HT ₃ Receptor	Depressive Disorder (1L)						Global	To begin enrollment in Q1 2025
	VV119	Voltage-gated Sodium Channel and Voltage-gated Calcium Channel (Presumed) ⁷	Epilepsy (1L)						Global	To initiate Phase II in 1H 2027
	VV119	5-HT Receptors, Dopamine Receptors and 5-HTT	Schizophrenia (1L)						Global	To initiate Phase II in 1H 2026
	VV147	Confidential	Depressive Disorder						Global	To submit IND in 1H 2026
Reproductive Health	TPN171	PDE5	ED (1L)					China	Global	To receive marketing approval in China in mid-2025
	VV913	Confidential	Premature Ejaculation					Uzbekistan	Global	To submit IND by the end of 2025

★ Core Products

Abbreviations: 1L = first-line; N/A = not applicable; 5-HTT = serotonin transporter; 5-HT₃ = 5-hydroxytryptamine 3; PDE = phosphodiesterase; CDE = Centre for Drug Evaluation; IND = investigational new drug application; RSV = respiratory syncytial virus; ED = erectile dysfunction; Q2 = second quarter; 1H = first half; 2H = second half; mid-2025 = second to third quarter of 2025.

Notes:

- VV116 received conditional marketing approval in China for the treatment of COVID-19 under the trade name 民得維® in January 2023, and received full approval in January 2025, and secured marketing approval in Uzbekistan for the treatment of moderate and severe COVID-19 under the trade name MINDVY® in December 2021.

SUMMARY

2. We co-discovered VV116 in collaboration with Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS. We acquired exclusive global intellectual property rights related to VV116 from Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS. For details, see “Business — Collaboration Arrangement — VV116 Agreements.” Starting in September 2021, we entered into a series of agreements with Junshi Biosciences, granting exclusive global rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19, with the exception of five countries in Central Asia (Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan), and Russia. For details, see “Business — Collaboration Arrangement — VV116 Agreements.”
3. Under a co-development agreement, we jointly own the rights to research, develop, manufacture, and commercialize VV116 for COVID-19 treatment with the Xinjiang Technical Institute of Physics and Chemistry, CAS in five Central Asian countries (Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan). For details, see “Business — Collaboration Arrangement — VV116 Agreements.”
4. We were heavily involved in the development of VV116 for the treatment of COVID-19 and are currently conducting clinical development for the treatment of RSV infection in China.
5. We hold exclusive global rights to research, develop, manufacture, and commercialize TPN171, LV232, VV261, TPN102, VV119, and VV913. We discovered and are internally developing VV119. For TPN171 and LV232, our founder Dr. Tian has made significant contributions to their discovery while he was working at Topharman Shanghai. We acquired exclusive global intellectual property rights related to TPN171 from Shanghai Institute of Materia Medica, CAS, Topharman Shanghai, and Shandong Topharman and acquired exclusive global intellectual property rights related to LV232 from Shanghai Institute of Materia Medica, CAS, and Topharman Shanghai. For details, see “Business — Collaboration Arrangement.” For VV261, TPN102, and VV913, we co-discovered these products with Topharman Shanghai and/or Independent Third Party partners, and subsequently acquired exclusive global rights. Regarding VV207 and VV147, we co-discovered these candidates with Independent Third Party partners and jointly own the global rights to research, develop, manufacture, and commercialize them.
6. Except for depressive disorder, epilepsy, schizophrenia and ED, currently there are no guidelines with respect to the treatment lines of the other indications targeted by our pipeline products, according to CIC.
7. According to preclinical studies, TPN102 demonstrated inhibitory activity on two ion channel receptors — sodium and calcium channels — at micromolar levels *in vivo*. Furthermore, TPN102 exhibited significant antiepileptic effects in various animal models of epilepsy, suggesting that both sodium and calcium channels may be the potential targets for TPN102. Based on data observed in these preclinical studies, as of the Latest Practicable Date, we believed that TPN102 targeted sodium and calcium channels.

SUMMARY

BUSINESS MODEL

We are a fully-integrated biopharmaceutical company with end-to-end capabilities spanning the entire industry value chain from research and clinical development to manufacturing and commercialization. Our core business model involves discovering, developing and commercializing innovative small molecule drugs in our strategically focused therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health.

We implement an innovation-oriented and flexible R&D approach which encompasses co-discovering or internally discovering and developing innovative drug candidates that address unmet medical needs by offering outstanding therapeutic efficacy and favorable safety profile. Building upon our co-discovery partnerships, we have established a proven track record in successfully advancing scientific discoveries into clinical applications — from bench to bedside, which is a validation of our robust R&D capabilities. Meanwhile, we believe that our co-discovery partnerships allow us to leverage the complementary strengths and resources of us and our partners to foster mutual value creation.

In addition to our innovative pipeline, we are also advancing a generic drug pipeline, which serves as a strategic complement to our business by generating visible and recurring revenue streams and cash flows, thereby enhancing our overall resilience.

Our fully-integrated capabilities are also reflected in our established manufacturing and commercial capabilities. We have established a GMP-standard commercial-scale in-house manufacturing facility located in Lianyungang, Jiangsu Province, with an aggregate GFA of approximately 51,955 sq.m. and an annual designed manufacturing capacity of 100 million capsules and 600 million tablets. We believe that our in-house manufacturing capability enhances the efficiency of our development and manufacturing processes, allowing us to achieve reliable quality and cost control and ensure stable and timely clinical and commercial drug supply to weather any supply chain disruptions. In addition, our house GMP-standard manufacturing capability will continue to serve as a bedrock for our capability to rapidly respond to evolving and unanticipated public health emergencies. We have established a dedicated business development and commercialization team of 14 employees with an average of more than 13 years of industry experience as of September 30, 2024. We believe that our in-house commercial capabilities will provide strong support for the upcoming commercialization of our drug candidates. Moreover, we proactively pursue licensing and collaboration arrangements with leading industry players to maximize the clinical and commercial value of our assets, exemplified by out-licensing agreements with Junshi Biosciences. See “Business — Collaboration Arrangement” for more details.

OUR PIPELINE

We take a systematic, patient- and indication-oriented approach to target prevalent or hard-to-treat diseases closely relating to the quality of life, and other diseases and conditions affecting a large and underserved population. Guided by this approach, we have strategically selected and focused on three therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health. According to CIC, the antiviral drug market, neuropsychiatric drug market and reproductive health drug market in China are forecasted to increase from

SUMMARY

RMB24.9 billion, RMB107.5 billion and RMB34.2 billion in 2023, respectively, to RMB44.9 billion, RMB137.5 billion and RMB39.8 billion in 2035, respectively. Despite the significant growth, there still exist considerable challenges in developing successful therapies in these therapeutic areas, presenting huge unmet clinical needs and substantial market opportunities for innovative treatments.

As of the Latest Practicable Date, we had built a highly competitive and differentiated pipeline of nine innovative assets, including two in commercial or near-commercial stage, four in clinical stage and three in preclinical stage. Our Core Products VV116, LV232 and TPN171 are specifically targeting the antiviral drug market, the neuropsychiatric drug market, and the reproductive health drug market, respectively, and are poised to address significant clinical needs.

VV116

VV116 is a RdRp inhibitor which has been approved for the treatment of COVID-19 in China and Uzbekistan under the trade names 民得維[®] and MINDVY[®], respectively, and is currently under Phase II/III clinical development for the treatment of RSV infection in China. RdRp, an enzyme that catalyzes the replication of RNA from an RNA template and highly conserved in various known RNA viruses, is a promising target for antiviral drugs with better adaptability to emerging variants.

The robust therapeutic efficacy of VV116 for COVID-19 treatment was well evidenced by its Phase III clinical results, which were published in influential journals, including The New England Journal of Medicine and The Lancet Infectious Diseases. In particular, data showed that VV116 was noninferior to Paxlovid in reducing the time to sustained clinical symptom resolution among patients with mild-to-moderate COVID-19 at risk for progression with improved safety profile. As of the Latest Practicable Date, 10 small molecule antiviral drugs were fully approved or conditionally approved globally for the treatment of COVID-19, with two of them having received full marketing approval in China. 民得維[®]/MINDVY[®] is the only product that has gained full approval both in China and internationally. For details of the market opportunity and competition of VV116 for the treatment of COVID-19, see “Industry Overview — Innovative Small Molecule Drug Industry — Antiviral Drugs — COVID-19 Drugs.”

As of the Latest Practicable Date, we were conducting a Phase II/III clinical trial of VV116 dry suspension in RSV-infected infants and young children aged one to 24 months. RSV is a RNA virus that could pose a persistent threat to children, the elderly and immunocompromised population. There were 25.5 million RSV infection cases in China and 136.2 million globally in 2023, according to CIC. However, there is no innovative small molecule antiviral drug approved for RSV infection globally. As of the Latest Practicable Date, VV116 was the only clinical-stage drug candidate for the treatment of RSV infection targeting RdRp in China. For details of the market opportunity and competition of VV116 for the treatment of RSV, see “Industry Overview — Innovative Small Molecule Drug Industry — Antiviral Drugs — RSV Drugs.”

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Preclinical studies have demonstrated that VV116 exhibits inhibitory activity against the original SARS-CoV-2 strain and various known variants, including Alpha, Delta and Omicron, as well as a broad-spectrum of RNA viruses, including Zika virus and Ebola virus. These findings suggest that the clinical application of VV116 could be significantly expanded to address challenging and high-risk viral infection, potentially including the treatment of co-infections involving multiple RNA viruses. Also, the synergistic effects of VV116 when combined with other antiviral drugs, such as nirmatrelvir, a 3C-like protease inhibitor, has been preliminarily validated in preclinical studies, indicating its potential to serve as a backbone drug in the antiviral therapeutic area. For details of VV116, see “Business — Innovative Drug Candidates — Core Product — VV116 — RNA-Dependent RNA Polymerase Inhibitor.”

LV232

LV232 is a potential first-in-class dual-target 5-HTT/5-HT₃ receptor modulator. With a unique mechanism of action, the two targets of LV232 work synergistically, enhancing the antidepressant effects while reducing the severity of common gastrointestinal side effects, such as nausea and vomiting. We plan to initiate a Phase II clinical trial of LV232 for the treatment of depressive disorder in China in the first quarter of 2025.

According to GBD2021, in China, the number of depressive disorder patients increased from 48.2 million in 2018 to 50.4 million in 2023, and is expected to further grow to 53.1 million in 2035. The global prevalence of depressive disorder patients increased from 303.7 million in 2018 to 355.3 million in 2023, and is expected to further grow to 399.4 million in 2035, according to CIC. As of the Latest Practicable Date, 24 innovative small molecule antidepressants had been approved for marketing in China. However, according to CIC, unmet clinical needs exist with up to 40% of patients failing to achieve full recovery, leading to recurring symptoms. As of the Latest Practicable Date, there were 14 innovative small molecule antidepressants under Phase II or later stage clinical development in China. LV232, an inhibitor of 5-HTT and an antagonist of 5-HT₃ receptor, was the only product exclusively targeting both the 5-HTT and 5-HT₃ receptor, underscoring its unique mechanism of action. For details of the market opportunity and competition of LV232, see “Industry Overview — Innovative Small Molecule Drug Industry — Neuropsychiatric Drugs — Anti-depression Drugs.”

Compared to currently marketed antidepressants, LV232 is expected to reduce gastrointestinal side effects and potentially improve patient compliance. In more than 100 healthy subjects in the completed Phase I clinical trials of LV232, all adverse reactions were in Grade 1 severity and fully reversible. Given its high safety profile and patient adherence, LV232 is expected to have an extremely low discontinuation rate, which could significantly improve its effectiveness in treating depression. In addition, according to preclinical studies in various depression animal models, LV232 demonstrated significant antidepressant effects at lower doses compared to positive control, an antidepressant that selectively blocks serotonin reuptake. Additionally, LV232 exhibited preliminary efficacy in animal models of anxiety and pain. For details of LV232, see “Business — Innovative Drug Candidates — Core Product — LV232 — Potential First-in-Class, 5-HTT/5-HT₃ Receptor Modulator.”

SUMMARY

TPN171

TPN171 is a potential best-in-class, highly potent and highly selective PDE5 inhibitor, which has been approved for the treatment of ED in Uzbekistan. We filed an NDA for TPN171 for the treatment of ED in China in September 2023, and we anticipate to obtain NDA approval around mid-2025.

According to CIC, PDE5 inhibitors are the standard first-line treatment for ED with the global PDE5 inhibitor market reaching US\$10.0 billion in 2023. The PDE5 inhibitor market in China grew rapidly from RMB5.5 billion in 2018 to RMB9.3 billion in 2023, representing a CAGR of 11.2%, and is expected to continue to increase significantly with a CAGR of 4.2% to reach RMB15.2 billion in 2035. As of the Latest Practicable Date, the FDA approved four PDE5 inhibitors for the treatment of ED: sildenafil from Pfizer, vardenafil from Bayer, tadalafil from Eli Lilly, and avanafil from Metuchen. In China, the NMPA approved these four PDE5 inhibitors as well as aildenafil from Youcare Pharmaceutical Group for ED treatment. Despite the enormous market demands, the currently approved PDE5 inhibitors exhibit strong inhibitory activity on other PDE isozymes, leading to common adverse effects that may negatively affect patient compliance and cause safety concerns. As of the Latest Practicable Date, there were seven PDE5 inhibitors under development for ED treatment in China. TPN171 stood out as one of the two product candidates that submitted NDA applications. For details of the market opportunity and competition of TPN171, see “Industry Overview — Innovative Small Molecule Drug Industry — Reproductive Health Drugs — PDE5 Inhibitors.”

TPN171 has demonstrated impressive efficacy and safety profiles in its clinical trials. Based on the results from our Phase III clinical trial, TPN171 improved erection function significantly in all dosage groups (2.5 mg/5 mg/10 mg) with the lowest dosage being 2 to 80 times lower than those of comparable PDE5 inhibitors. As a non-head-to-head comparison, such results showed TPN171 potentially demonstrated better efficacy at a lower dose compared to marketed PDE5 inhibitors in China. In addition, based on a non-head-to-head comparison, data collected from a Phase III clinical study in all TPN171 dose groups showed that the incidence of headache, flushing and gastrointestinal adverse events was lower than that observed with comparable PDE5 inhibitors, with no occurrence of common adverse reactions such as back pain, myalgia or visual abnormalities. This suggests that TPN171 may offer improved safety profile and thus enhanced patient adherence.

TPN171 offers superior patient compliance with an onset time as short as half an hour. Meanwhile, with a half-life of 8 to 11 hours, TPN171 is expected to have a relatively long duration of action. Also, Phase I clinical trial results showed that certain special populations did not require dosage adjustments and TPN171 absorption was not affected by a standard meal, a high-fat diet or moderate amount of alcohol consumption. For details of TPN171, see “Business — Innovative Drug Candidates — Core Product — TPN171 — Potential Best-in-Class, Highly Selective, Highly Potent PDE5 Inhibitor.”

SUMMARY

Other Pipeline Products

Below is an introduction of our innovative drug candidates in early clinical development stage:

- **VV261** is a broad-spectrum antiviral nucleoside prodrug targeting RdRp of viruses. Once administered, it is converted into its active nucleoside triphosphate form, which inhibits the RdRp of the severe fever with thrombocytopenia syndrome virus (“SFTSV”), disrupting the virus’ transcription and genome replication processes to effectively treat SFTSV infection. The active form of VV261 targets the highly conserved active site of the viral polymerase, exerting its antiviral effects and reducing the likelihood of viral resistance. Preclinical studies have demonstrated that VV261 possesses potent *in vitro* and *in vivo* activity against SFTSV, with advantages such as high oral bioavailability and suitability for oral administration. Furthermore, VV261 exhibited broad-spectrum antiviral potential, showing strong inhibitory effects against a range of RNA viruses, including coronavirus, influenza virus, arenavirus, and RSV. In August 2024, we obtained the IND approval from NMPA for conducting Phase I and Phase II clinical trials of VV261 for the treatment of SFTSV. As of the Latest Practicable Date, VV261 was in Phase I clinical stage.
- **TPN102** is a voltage-gated sodium and calcium channels inhibitor for the treatment epilepsy, targeting to suppress both generalized and focal seizures. Blocking voltage-dependent ion channels reduces the depolarization threshold of the cell membrane in the brain, making it more difficult for neurons to become excited. This mechanism helps treat epilepsy, which is characterized by neuronal depolarization. Preclinical studies of TPN102 has demonstrated improved efficacy than current available antiepileptic drugs and much weaker inhibitory activity on carbonic anhydrase II, indicating it can be more suitable for children with epilepsy. We obtained IND approval for conducting Phase I and Phase II clinical trials of TPN102 for the treatment of epilepsy from the NMPA in June 2018. As of the Latest Practicable Date, TPN102 was in Phase I clinical stage.
- **VV119** is an independently discovered, multi-target serotonin-dopamine activity modulator for the treatment of psychiatric disorders, especially schizophrenia. As a prodrug, VV119 and its major active metabolite can act through a combination of antagonistic activity at the D₃ receptor, partial agonistic activity at the D₂ receptor, partial agonistic activity at the 5-HT_{1A} receptor, antagonistic activity at the 5-HT_{2A} receptor, and inhibitory activity on the 5-HT transporter. VV119 adopted a multi-target strategy and acts as a serotonin-dopamine activity modulator. It has a long half-life and holds potential for development as a long-acting formulation. Preclinical data has shown that VV119 may improve positive symptoms, negative symptoms, and cognitive function in schizophrenia while also reducing the risk of extrapyramidal side effects. These potential clinical benefits position VV119 as an enhanced treatment option, promoting better patient adherence. We received IND

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approval for conducting Phase I and Phase II clinical trials of VV119 for the treatment of schizophrenia from the NMPA in September 2023. As of the Latest Practicable Date, VV119 was in Phase I clinical stage.

Below is an introduction of our innovative drug candidates in preclinical studies:

- **VV207** is an orally administered nucleoside prodrug with a novel structure, exhibiting broad-spectrum antiviral activity against DNA viruses, including adenovirus, poxvirus, herpesvirus, and hepatitis B virus, with an EC_{50} in the nanomolar range. Adenovirus is a double-stranded DNA virus that is widely distributed in mammals and birds. It is highly infectious, spreads easily, and can cause a range of diseases, such as adenoviral pneumonia, acute conjunctivitis, gastroenteritis, and cystitis. Currently, no effective or targeted vaccines or therapeutic agents are approved for adenovirus infections. Treatment primarily focuses on symptomatic relief and preventing secondary infections, but these approaches often yield unsatisfactory results. As such, there is an urgent global need for antiviral drugs with a well-defined mechanism of action, significant therapeutic efficacy, and high barrier to resistance.
- **VV147** is designed to provide rapid therapeutic effects in the treatment of depressive disorder. Depression is a mood disorder marked by high incidence, frequent relapses, and significant disability, which has a profound impact on public health. Despite advances in treatment, clinical management of depression still faces several challenges. Notably, many commonly prescribed antidepressants have a delayed onset of action, typically requiring 2 to 4 weeks of administration before showing noticeable effects. This delay often results in higher rates of treatment discontinuation and lower patient adherence, which severely impedes the successful management of depression. While esketamine, an adjunctive treatment for depression, offers a rapid onset, its potential for abuse limits its clinical use. Preclinical studies have shown that a single oral dose of VV147 exhibits significant antidepressant-like effects in various chronic depression models, including chronic unpredictable mild stress and chronic social defeat stress, with promising rapid onset potential. Additionally, VV147 demonstrated no addictive-like effects in the conditioned place preference model, suggesting improved accessibility compared to esketamine.

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- **VV913** is a small molecule with a novel structure designed for the treatment of premature ejaculation (“**PE**”), a common male sexual dysfunction that can significantly affect patients’ quality of life. Pharmacological treatment is the first-line approach for PE, with dapoxetine being the only approved oral medication. However, dapoxetine is associated with side effects such as nausea, dizziness, and reduced libido, highlighting the urgent need for the development of faster-acting and safer alternatives. Preclinical *in vivo* studies have indicated that VV913 is effective in treating PE and offers the benefit of on-demand dosing. In the preclinical studies, it demonstrated significant efficacy in a rat model of PE, where a single dose notably extended ejaculation latency and reduced ejaculation frequency, showing promise for on-demand use. Furthermore, in balance beam and sexual arousal tests, compared to dapoxetine, VV913 demonstrated favorable safety with a much lower risk of side effects, such as dizziness and decreased libido, than those of dapoxetine in male rats.

In addition, we have also developed or are developing a pipeline of four generic products:

- **Dapoxetine** is a selective serotonin reuptake inhibitor used in the treatment of PE. In October 2023, we received marketing approval from the NMPA for the finished dosage form, dapoxetine hydrochloride tablets (30mg).
- **Rebamipide** is an endogenous mucosal protective agent for the treatment of various gastrointestinal diseases. We obtained marketing approval from the NMPA in November 2024.
- **Brexiprazole** is a 5-HT/DA activity modulator that exhibits partial agonist activity at the 5-HT_{1A} and D₂ receptors, along with an antagonistic effect at the 5-HT_{2A} receptor. In July 2024, we submitted an ANDA for marketing approval to the NMPA, with approval expected in the second half of 2025.
- **Letermovir** is a novel inhibitor that targets the cytomegalovirus (“**CMV**”) DNA terminase, blocking its ability to cleave newly synthesized CMV DNA into individual viral genomes and package them into empty viral capsids, thereby inhibiting viral replication. We are currently conducting laboratory-scale testing, with pilot-scale production scheduled to begin in the first quarter of 2025.

For details regarding our generic pipeline products, see “Business — Generic Drug Pipeline.”

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OUR PLATFORMS

Our proprietary technology platforms focus on (i) rapid discovery of innovative therapeutic compounds, and (ii) investigation and optimization of the discovered compounds. We believe our technology platforms enable us to identify and address potential clinical and manufacturing issues early in the development process so we can direct our efforts towards compounds with the best potential to become clinically active, cost-effective and commercially viable drugs. Highlights of our proprietary technology platforms include:

- **Innovative drug discovery platform for viral infection:** With the aim to promptly address currently identified viral infection and future potential viral outbreaks with significant public health burdens, we have developed an innovative drug discovery platform for viral infectious diseases, incorporating two key technologies: nucleoside analogs design technology and prodrug design technology. In particular, nucleoside analogs, through the function of polymerases, incorporate phosphorylated nucleosides into newly synthesized viral genomes, resulting in the termination of the viral DNA or RNA extension or induces lethal mutations, thereby exerting antiviral effects. However, the rational design of antiviral nucleoside analog presents significant challenges. We have synthesized numerous nucleoside analogs with diverse structures and conducted extensive antiviral activity studies targeting DNA and RNA viruses. Leveraging these studies, we have developed a nucleoside analogs design technology aimed at enhancing antiviral activity, minimizing toxicity, optimizing pharmacokinetic properties, and identifying scenarios where phosphorylation modifications are necessary.
- **Innovative drug discovery platform for neuropsychiatric disorders:** With the aim to address challenges in developing effective therapies for neuropsychiatric disorders, we have independently developed a platform featuring core technologies including multi-target strategy-based drug discovery, diversified new drug *in vivo* evaluation system and enhanced compound BBB permeability. Specifically, the pathogenesis of neuropsychiatric disorders is complex, therefore, targeting a single pathway may not cure the diseases. Based on our insights of the pathogenesis of these diseases, we have identified appropriate target combinations and developed a multi-target strategy for innovative drug discovery. Using this technology, we have discovered VV119, a multi-target compound that target multiple pathways to exert a synergistic effect. In addition, developing animal models based on different causes and conducting comprehensive behavioral evaluations are key to improving the success rate of drug development in this area. We have successfully established a diversified *in vivo* evaluation system for new drugs targeting neuropsychiatric disorders, which enable us to systematically assess the efficacy of candidate compounds and comprehensively evaluate potential side effects during the preclinical stage. We have utilized our *in vivo* evaluation system as an integral part of our drug development process. For example, we have employed this system to evaluate the efficacy of LV232 and VV119.

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- **Innovative drug discovery platform for reproductive health diseases:** Our drug discovery platform for reproductive health diseases features (i) pharmacokinetics guided “structural fine-tuning” technology that aims to achieve an optimal balance of compound activity and pharmacokinetic properties and (ii) sexual dysfunction animal model construction technology with a variety of independently developed animal models to systematically evaluate the pharmacological efficacy of candidate compounds.
- **“Control from root design” oriented green synthesis process R&D platform:** Synthetic route design is the crucial element in the synthesis process of API. We have developed our “control from root design” oriented green synthesis process R&D platform, which primarily focuses on synthetic route design with a comprehensive consideration of regulatory requirements, chemical and process factors and environmental impact. By adopting our “control from root design” strategy, our synthesis processes and conditions reinforces our competitive edge within the industry and support green and sustainable development.

For details of the technology platforms, see “Business — Our Proprietary Technology Platforms.”

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors:

- Fully-integrated biopharmaceutical company with a highly competitive and differentiated pipeline of innovative assets to capture substantial market opportunities in three strategically focused therapeutic areas;
- Three Core Products with first- or best-in-class potential, outstanding therapeutic efficacy and extensive indication expansion opportunities;
- Robust in-house R&D capabilities empowered by proprietary technology platforms, fueling continuous innovation;
- GMP-standard commercial-scale in-house manufacturing capability, ensuring stable and cost-controllable supply;
- Strong commercial capabilities to facilitate effective market entry and penetration; and
- Visionary management team with rich industry experience and scientific expertise, backed by well-known investors.

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OUR STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following strategies:

- Rapidly advance the clinical development of our drug candidates;
- Continue to enhance our R&D capabilities and further expand our pipeline;
- Further enhance our GMP-compliant manufacturing capability; and
- Continue to strengthen our commercial capabilities and explore partnership opportunities to maximize the value of our pipeline assets.

RESEARCH AND DEVELOPMENT

We consistently devote resources to research and development to pave for long-term growth. We believe the diversification and expansion of our product pipeline through both in-house research and development and external collaborations are critical to our long-term competitiveness and success. In 2023 and the nine months ended September 30, 2024, the amount of research and development expenses attributed to our Core Products was RMB50.3 million and RMB42.4 million, respectively, accounting for 38.3% and 42.2% of our total research and development expenses in the respective period. Our R&D centers, located in Suzhou and Shanghai with an aggregate GFA of over 8,000 sq.m., are equipped with advanced laboratories and state-of-art equipment and instruments.

As of September 30, 2024, we have established a dedicated in-house R&D team of 148 members with an average of more than 10 years of industry experience and more than 50% of our R&D team members held master’s or above degrees. The functions of our R&D team span the entire spectrum of hit discovery, lead optimization, druggability evaluation and PCC identification, preclinical research, chemistry, manufacture, and controls processes (“CMC”) development, clinical study and regulatory affairs. All the key R&D team members involved in the development of our Core Products have been with us throughout the Track Record Period and up to the Latest Practicable Date.

Our R&D team is led by Dr. Tian, our founder, chairman of the Board, executive Director, chief executive officer and general manager of our Company, having accumulated over 20 years of robust experience in the pharmaceutical industry. Dr. Tian has been appointed as an industrial professor by Suzhou University and was awarded as a “Key Industry Urgently-needed Talent (重點產業緊缺人才)” by Suzhou government authorities. In addition, Dr. Tian led or participated in a number of national scientific research projects, such as Major Science and Technology Special Project for “Significant New Drugs Development” (“重大新藥創制”科技重大專項) and the National High-tech R&D Program (“863 Program”). Dr. Tian obtained his doctor’s degree in medicinal chemistry from Shanghai Institute of Materia Medica, CAS.

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In addition to Dr. Tian, core members of our R&D team also include Dr. Hu Tianwen, Dr. Wang Zhiqiang and Dr. Yang Rulei. Dr. Hu, our deputy general manager mainly responsible for the management and R&D strategy of our Group, has more than 10 years of experience in R&D of innovative drugs. As a prolific author, Dr. Hu has published more than 20 Science Citation Index (SCI) research papers. In addition, Dr. Hu has participated in a number of provincial science and technology projects as project leaders or core members. Dr. Hu obtained his doctor’ degree in organic chemistry from the Xinjiang Technical Institute of Physics and Chemistry Technology of the CAS. Dr. Wang, our deputy general manager mainly responsible for the supervision and execution of clinical trials, has more than 20 years of experience in R&D of innovative drugs. Dr. Wang has led the clinical development and regulatory submissions for more than 10 innovative drugs. Dr. Wang obtained his doctor’ degree in pharmacology from China Pharmaceutical University (中國藥科大學). Dr. Yang, head of our manufacturing team, has more than 10 years of industry experience. Before joining us, Dr. Yang worked in prominent pharmaceutical companies such as Suzhou Kelun Pharmaceutical Research Co., Ltd. (蘇州科倫藥物研究有限公司), Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (正大天晴藥業集團股份有限公司) and Suzhou Suncadia Biopharmaceutical Co., Ltd. (蘇州盛迪亞生物醫藥有限公司) (a wholly-owned subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江蘇恒瑞醫藥股份有限公司)). Dr. Yang obtained his doctor’s degree in Chinese medicines from Nanjing University of Chinese Medicine (南京中醫藥大學).

MANUFACTURING

As of the Latest Practicable Date, we have one manufacturing facility (“**Lianyungang Facility**”) located in Lianyungang, Jiangsu Province, with an aggregate GFA of approximately 51,955 sq.m., housing one workshop for small molecule drugs in oral solid dosage forms and one workshop for APIs. Our Lianyungang Facility has obtained GMP certificate. Lianyungang Facility commenced operations in June 2024 with an annual designed manufacturing capacity of 100 million capsules and 600 million tablets.

COMMERCIALIZATION

During the Track Record Period and up to the Latest Practicable Date, we sold dapoxetine to pharmacy chains in China directly or indirectly through distributors, as well as VV116 to corporate and individual customers in Uzbekistan. Our in-house sales and marketing team is primarily responsible for the promotion of our products through various marketing activities and sales through different channels in China and Uzbekistan.

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INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we had 22 registered trademarks, three trademark applications and three domain names, which we consider to be material to our business. As of the Latest Practicable Date, we held 81 issued patents including 39 issued patents in China and 42 issued patents in other jurisdictions, and 78 patent applications including 35 patent applications in China, 36 patent applications in other jurisdictions, and seven patent applications under PCT. As of the Latest Practicable Date, for our Core Products, we held 31 issued patents including eight issued patents in China and 23 issued patents in other jurisdictions, and 30 patent applications including six patent applications in China and 24 patent applications in other jurisdictions. For further details, please see “Business — Intellectual Property.”

OUR CUSTOMERS

Our customers primarily consist of our out-licensing customers, as well as our direct sales customers and distributors which directly purchase pharmaceutical products from us, as well as pharmaceutical companies to which we provide CRO services. In 2023 and the nine months ended September 30, 2024, our revenue generated from our five largest customers in each year/period during the Track Record Period in aggregate accounted for 99.3% and 94.2% of our total revenue in the respective year/period, respectively, and revenue generated from our largest customer alone in each year/period during the Track Record Period accounted for 51.1% and 79.9% of our total revenue in each respective year/period, respectively. To the best of knowledge of our Directors, all of our five largest customers in each year/period during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest customers in each year/period during the Track Record Period. For further details, please see “Business — Customers.”

OUR SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of (i) IP assignors; (ii) suppliers of raw materials and consumables for the R&D of our drug candidates; (iii) suppliers of APIs, excipients and packaging materials for the manufacturing of our drugs; and (iv) third party contractors including CROs and CMOs. In 2023 and the nine months ended September 30, 2024, our purchases from our five largest suppliers in each year/period during the Track Record Period in aggregate accounted for 36.5% and 44.7% of our total purchases in the respective year/period, respectively, and purchases from our largest supplier alone in each year/period during the Track Record Period accounted for 16.5% and 24.5% of our total purchases in each respective year/period, respectively. To the best of knowledge of our Directors, except for Shandong Topharman, all of our five largest suppliers in each year/period during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers in each year/period during the Track Record Period, except for Shandong Topharma. For further details, please see “Business — Raw Materials and Suppliers.”

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SUMMARY OF MATERIAL COLLABORATION ARRANGEMENTS

VV116 Agreements

Starting in October 2020, we entered into a series of agreements, including a technology transfer agreement and supplemental agreements (the “**VV116 Assignment Agreements**”), with Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS (the “**VV116 Assignors**”), acquiring exclusive intellectual property rights related to VV116 controlled by the VV116 Assignors on a global scale. The VV116 Assignors are Independent Third Parties. We became acquainted with them through our founder Dr. Shen, who is a researcher, group leader, and doctoral supervisor at Shanghai Institute of Materia Medica, CAS.

Starting in September 2021, we entered into a series of agreements (the “**VV116 Out-Licensing Agreements**”) with Junshi Biosciences, out-licensing the acquired exclusive rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 on a global scale, except for four regions or countries: five countries in Central Asia (i.e., Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (i.e., Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (i.e., Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan), and Russia (the “**Company Regions**”). Junshi Biosciences is an Independent Third Party. We became acquainted with Junshi Biosciences through our shared goal of developing a therapeutic product for the treatment of COVID-19.

In March 2022, we entered into an agreement with Xinjiang Technical Institute of Physics and Chemistry, CAS (the “**VV116 Co-Developer**”) to co-develop VV116 for the treatment of COVID-19 in the five countries in Central Asia (the “**VV116 Collaboration Agreement**”). The VV116 Co-Developer is an Independent Third Party. We became acquainted with the VV116 Co-Developer due to the shared goal of developing and commercializing a COVID-19 treatment drug in Uzbekistan in response to the PRC government’s Belt and Road Initiative.

LV232 Agreements

In 2021 and 2023, Nantong Hefeng entered into a transfer agreement and a supplemental agreement (the “**LV232 Agreements**”) with Shanghai Institute of Materia Medica, CAS, and Topharman Shanghai (the “**LV232 Assignors**”), acquiring exclusive intellectual property rights related to LV232 controlled by the LV232 Assignors on a global scale. Topharman Shanghai is controlled by our founder, Dr. Shen.

TPN171 Agreements

Starting in 2017, we entered into a series of agreements, including a technology development and a supplemental agreement (the “**TPN171 Agreements**”) with Shanghai Institute of Materia Medica, CAS, Topharman Shanghai, and Shandong Topharman (the “**TPN171 Assignors**”), acquiring exclusive intellectual property rights related to TPN171 controlled by the TPN171 Assignors on a global scale. Shandong Topharman is controlled by our founder Dr. Shen.

For detailed information regarding these agreements, see “Business — Collaboration Arrangement.”

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SUMMARY OF HISTORICAL FINANCIAL INFORMATION

This summary of key financial information set forth below has been derived from, and should be read in conjunction with, our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix IA and unaudited financial information for the nine months ended September 30, 2024 included in Appendix IB to this document, as well as the information set forth in “Financial Information.”

Summary Consolidated Statements of Profit or Loss and Comprehensive Income

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i> <i>(unaudited)</i>	<i>RMB’000</i> <i>(unaudited)</i>
Revenue	199,651	194,387	9,996
Cost of sales	<u>(6,014)</u>	<u>(5,399)</u>	<u>(6,210)</u>
Gross profit	193,637	188,988	3,786
Other income	5,974	2,284	7,271
Other gains and losses, net	222	(4)	176
Research and development expenses	(131,297)	(102,007)	(100,481)
Administrative expenses	(51,187)	(39,425)	(50,936)
Selling expenses	(1,322)	(776)	(2,933)
Impairment losses under ECL model, net of reversal	(2,400)	(2,673)	(1,269)
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Finance costs	<u>(7,200)</u>	<u>(4,016)</u>	<u>(11,986)</u>
Profit/(loss) before tax	6,427	42,371	(156,372)
Income tax expense	<u>–</u>	<u>–</u>	<u>–</u>
Profit/(loss) for the year/period	<u>6,427</u>	<u>42,371</u>	<u>(156,372)</u>
Exchange differences arising on translation of foreign operations	<u>(285)</u>	<u>(209)</u>	<u>(240)</u>
Total comprehensive income/(expenses) for the year/period	<u>6,142</u>	<u>42,162</u>	<u>(156,612)</u>
Profit/(loss) for the year/period attributable to:			
Owners of the Company	12,089	48,510	(150,866)
Non-controlling interests	<u>(5,662)</u>	<u>(6,139)</u>	<u>(5,506)</u>
	<u>6,427</u>	<u>42,371</u>	<u>(156,372)</u>

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Selected Items of Our Consolidated Statements of Financial Position

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated:

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Total non-current assets	510,112	562,134
Total current assets	166,184	154,730
Total assets	676,296	716,864
Total current liabilities	285,809	367,792
Net current liabilities	(119,625)	(213,062)
Total non-current liabilities	202,371	245,506
Total liabilities	488,180	613,298
Net assets	188,116	103,566
Equity attributable to owners of the Company	199,094	119,050
Non-controlling interests	(10,978)	(15,484)

For more information, see “Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position.”

Our net assets decreased from RMB188.1 million as of December 31, 2023 to RMB103.6 million as of September 30, 2024, primarily attributable to (i) loss for the period of RMB156.4 million mainly driven by the research and development expenses and administrative expenses we incurred, and (ii) the recognition of redemption liabilities of the shares held by one of the Series C investors of RMB50.0 million, partially offset by the issue of Series C shares of RMB110.0 million. See “Consolidated Statement of Changes in Equity” to the Accountants’ Report in Appendix IA and “Condensed Consolidated Statement of Changes in Equity for the Nine Months Ended September 30, 2024” set forth in unaudited financial information for the nine months ended September 30, 2024 to the Accountants’ Report in Appendix IB to this document.

Our net current liabilities increased from RMB119.6 million as of December 31, 2023 to RMB213.1 million as of September 30, 2024, primarily due to (i) an increase in financial liabilities at amortized cost mainly due to the redemption right granted by us to one of Series C investors; (ii) an increase in borrowings to support our operations; and (iii) a decrease in trade receivables, mainly because we received certain payments from milestones and assignment of rights in relation to VV116 during the first half of 2024, partially offset by a decrease in trade and other payables, mainly due to our settlement of the outstanding balances according to our acceptance progress of the manufacturing facility in Lianyungang.

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Summary Consolidated Statements of Cash Flows

The following table sets forth our consolidated statements of cash flows for the year/periods indicated:

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Cash generated from/(used in) operations before movements in working capital	47,366	72,344	(107,699)
Changes in working capital	<u>(16,697)</u>	<u>(28,179)</u>	<u>(3,203)</u>
Net cash flows generated from/(used in) operating activities	30,669	44,165	(104,466)
Net cash flows used in investing activities	(160,871)	(125,112)	(74,586)
Net cash flows generated from financing activities	<u>76,501</u>	<u>59,754</u>	<u>177,917</u>
Net decrease in cash and cash equivalents	(53,701)	(21,193)	(1,135)
Cash and cash equivalents at beginning of the year/period	149,429	149,429	95,974
Effect of foreign exchange rate changes	<u>246</u>	<u>16</u>	<u>213</u>
Cash and cash equivalents at end of the year/period	<u>95,974</u>	<u>128,252</u>	<u>95,052</u>

For details of our cash flows, see “Financial Information — Liquidity and Capital Resources — Cash Flows.”

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED], as well as cash burn rate, we have available sufficient working capital to cover at least 125% of the Group’s costs, including general, administrative and operating costs (including any production costs), research and development costs, and repayments to amounts due to a related party, for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly amount of (i) net cash used in operating activities, and (ii) capital expenditures. Assuming an average cash burn rate going forward of 2.1 times the level in 2023, taking into account that we have received net proceeds of RMB50.0 million from our Series C Financing in the fourth quarter of 2024, and the estimated net [REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per Share, being the

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low-end of the indicative [REDACTED] stated in this document), we estimate that our cash and cash equivalents as of September 30, 2024 will be able to maintain our financial viability for 35 months from September 30, 2024. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing at least six months after the completion of the [REDACTED].

KEY FINANCIAL RATIO

The table below sets forth the key financial ratio as of the dates indicated:

	<u>As of December 31,</u>	<u>As of September 30,</u>
	<u>2023</u>	<u>2024</u>
Current ratio ⁽¹⁾	0.6	0.4

Note:

(1) Current ratio equals to current assets divided by current liabilities as of the same date.

Our current ratio decreased from 0.6 as of December 31, 2023 to 0.4 as of September 30, 2024, primarily due to (i) an increase in financial liabilities at amortized cost, reflecting our obligation to return the investment and the relevant interest to one of our Series C investors with redemption rights; (ii) an increase in borrowings to support our operations; and (iii) a decrease in our trade receivables as we received certain payments from milestones and assignment of rights in relation to VV116 during the first half of 2024.

SUMMARY OF MATERIAL RISK FACTORS

We believe that there are certain risks involved in our operations, many of which are beyond our control. These risks are set out in the section headed “Risk Factors” in this document. Some of the major risks we face include:

- Our business and financial prospects depend substantially on the success of our clinical stage and preclinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.
- We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis.

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- We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our revenue and profitability and our ability to successfully commercialize our drug candidates.
- We have limited experience in the commercialization of drugs. If we are unable to maintain and expand an effective sales and distribution network for our drugs and future approved drug candidates, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our drugs and future approved drug candidates, which could negatively affect our ability to effectively sell them and would materially and adversely affect our business, results of operations, financial condition and prospects.
- We may not realize any or all benefits of collaboration, alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.
- We have limited experience in manufacturing pharmaceutical products on a large commercial scale, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.
- If we and our current or future collaborating partners are unable to protect our intellectual property rights worldwide, or if the scope of such intellectual property rights obtained is not sufficiently broad or a compulsory license is issued, third parties could develop and commercialize drug candidates and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially and adversely affected.
- All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated.
- We may continue to incur significant research and development expenses and other expenses related to our ongoing operations and not be able to generate sufficient revenue to achieve and maintain profitability in the future.

Given the high risks involved in our business and our industry in general, you may lose substantially all your [REDACTED] in us. You should read the entire section headed “Risk Factors” in this document before you decide to [REDACTED] in the [REDACTED].

SUMMARY

OUR CONTROLLING SHAREHOLDERS AND PRE-[REDACTED] INVESTMENTS

As of the Latest Practicable Date, Dr. Shen, a founder of our Company, was able to exercise approximately 54.97% voting rights in our Company through directly holding 82,461,110 Shares. Ms. Jin Jie (金潔), Dr. Shen’s spouse, was able to exercise approximately 1.52% voting rights in our Company through directly holding 2,272,478 Shares. Immediately upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Dr. Shen and Ms. Jin Jie will be entitled to exercise approximately [REDACTED]% voting rights in our Company in aggregate. Therefore, Dr. Shen and Ms. Jin Jie will be regarded as the Controlling Shareholders of our Company under the Listing Rules. For further details, see “Relationship with our Controlling Shareholders” in this document.

Throughout the development of our Company, we received several rounds of Pre-[REDACTED] Investments. Our broad and diverse base of Pre-[REDACTED] Investors include investors focusing on investment in biotech and healthcare industry, among which Xieyao Kexin, Xieyao Kesheng and Suzhou Meilingge are Sophisticated Investors. For further details of the identity and background of the Pre-[REDACTED] Investors, see “History, Development and Corporate Structure — Pre-[REDACTED] Investments” in this document.

CONNECTED TRANSACTIONS

We have entered into and are expected to continue with certain transactions which will constitute connected transactions under Chapter 14A of the Listing Rules upon [REDACTED]. See “Connected Transactions” in this document.

RECENT DEVELOPMENTS

The recent developments of our drug candidates since the end of the Track Record Period and up to the Latest Practicable Date include:

- In October 2024, we received the approval from the ethics committee for conducting a Phase I clinical trial of VV261 in healthy subjects;
- In November 2024, we obtained marketing approval of rebamipide from the NMPA;
- In December 2024, we received the approval from the ethics committee for conducting a Phase II clinical trial of LV232 in depression patients;
- In January 2025, we completed two Phase I clinical studies of LV232 in healthy subjects; and
- In January 2025, we published the relevant information of the Phase II clinical trial of LV232 for the treatment of depression through the official website of the CDE.

SUMMARY

No Material Adverse Change

Our Directors confirm that, there has been no material adverse change in our business, financial condition and results of operations since September 30, 2024, being the latest balance sheet date of our condensed consolidated financial statements for the nine months ended September 30, 2024 set out in Appendix IB to this document, and up to the Latest Practicable Date.

DIVIDEND

We did not declare or pay any dividend during the Track Record Period. We do not currently have a formal dividend policy or a fixed dividend payout ratio. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make, as determined in accordance with its articles of association and the accounting standards and regulations in China. As advised by our PRC Legal Adviser, taking into account the aforesaid, we may not have sufficient or any distributable profits to make dividend distributions to our Shareholders in a given year, in view of our accumulated losses, or even if we become profitable, as we will only be able to declare or pay dividends out of our distributable profits until (i) the accumulated losses are covered by our after-tax profits, and (ii) sufficient statutory and other reserves are drawn in accordance with the relevant laws, regulations and our constitutional documents. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay dividends out of our profits in the foreseeable future.

THE [REDACTED]

[REDACTED]

SUMMARY

[REDACTED]

[REDACTED] STATISTICS

	Based on an [REDACTED] of HK\$[REDACTED] per H Share	Based on an [REDACTED] of HK\$[REDACTED] per H Share
[REDACTED] of our Shares ⁽ⁱ⁾	HK\$[REDACTED]	HK\$[REDACTED]
Unaudited [REDACTED] adjusted consolidated net tangible assets per Share ⁽ⁱⁱ⁾	HK\$[REDACTED]	HK\$[REDACTED]

Notes:

- (i) The calculation of [REDACTED] is based on [REDACTED] Shares expected to be in issue immediately after completion of the [REDACTED], with the reference date being the [REDACTED]. For details, see “History, Development and Corporate Structure — Capitalization of Our Company” in this document.
- (ii) [REDACTED] For details, see Note 3 and 4 in “Financial Information — Unaudited [REDACTED] Statement of Adjusted Net Tangible Assets” and Note 3 and 4 in “Appendix II — Unaudited [REDACTED] Financial Information” in this document.
- (iii) No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets of our Group as of September 30, 2024 to reflect any trading result or other transactions of our Group entered into subsequent to September 30, 2024.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED], fees and other estimated expenses paid and payable by us in connection with the [REDACTED], assuming the [REDACTED] being not exercised and an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] stated in this document). we intend to use the net [REDACTED] from the [REDACTED] for the following purposes

- [REDACTED]%, or approximately HK\$[REDACTED], will be used for the research and development of our Core Products;

SUMMARY

- [REDACTED]%, or approximately HK\$[REDACTED], will be used for the research and development of our other product candidates;
- [REDACTED]%, or approximately HK\$[REDACTED], will be used for the construction of our Qingdao Facility;
- [REDACTED]%, or approximately HK\$[REDACTED] will be used for the reinforcement of our sales and marketing capabilities; and
- [REDACTED]%, or approximately HK\$[REDACTED], will be used for working capital and other general corporate purposes.

For more details, see “Future Plans and Use of [REDACTED].”

[REDACTED]

Our [REDACTED] represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Based on the [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED]), and assuming the [REDACTED] is not exercised, our [REDACTED] in relation to the [REDACTED] are estimated to be approximately RMB[REDACTED] (HK\$[REDACTED]), representing [REDACTED]% of the [REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per Share and assuming the [REDACTED] is not exercised). The [REDACTED] consist of (i) [REDACTED] expenses, including [REDACTED], of approximately RMB[REDACTED] (HK\$[REDACTED]), and (ii) [REDACTED] expenses of approximately RMB[REDACTED] (HK\$[REDACTED]), comprising (a) fees and expenses of our legal advisers and reporting accountants of approximately RMB[REDACTED] (HK\$[REDACTED]), and (b) other fees and expenses of approximately RMB[REDACTED] (HK\$[REDACTED]).

During the Track Record Period, we did not incur any [REDACTED]. We expect to incur [REDACTED] of approximately RMB[REDACTED] (HK\$[REDACTED]) after the Track Record Period, approximately RMB[REDACTED] (HK\$[REDACTED]) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] (HK\$[REDACTED]) of which is attributable to the issue of Shares and will be deducted from equity upon [REDACTED]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

DEFINITIONS

In this document, unless the context otherwise requires, the following terms and expressions shall have the meanings set out below. Certain technical terms are explained in the section headed “Glossary of Technical Terms” in this document.

“Accountant’s Report”	the accountants’ report of our Company for the Track Record Period prepared by Deloitte Touche Tohmatsu, the text of which is set out in Appendix IA to this document
“affiliate”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council of Hong Kong
“Articles of Association” or “Articles”	the articles of association of the Company adopted on January 24, 2025 which will become effective upon the [REDACTED] and as amended from time to time, a summary of which is set out in Appendix VI to this document
“associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Belt and Road Initiative”	a global infrastructure development strategy adopted by the Chinese government in 2013 to invest in more than 150 countries and international organizations, which is composed of six urban development land corridors linked by road, rail, energy, and digital infrastructure and the Maritime Silk Road linked by the development of ports
“Board” or “Board of Directors”	the board of Directors of our Company
“Business Day” or “business day”	a day on which banks in Hong Kong are generally open for normal business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong

[REDACTED]

DEFINITIONS

“CAS”	Chinese Academy of Sciences (中國科學院)
	[REDACTED]
“China” or “PRC”	the People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires otherwise, references in this document to “China” and the “PRC” do not include Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan
“CIC” or “Industry Consultant”	China Insights Industry Consultancy Limited, an independent market research and consulting company
“CIC Report”	the industry report commissioned by our Company and independently prepared by CIC, a summary of which is set forth in the section headed “Industry Overview” in this document
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Company” or “our Company”	Vigonvita Life Sciences Co., Ltd. (蘇州旺山旺水生物醫藥股份有限公司), a company established in the PRC on January 21, 2013 with limited liability and converted into a joint stock company with limited liability on April 28, 2023
“Company Law” or “PRC Company Law”	the Company Law of the PRC (《中華人民共和國公司法》), as amended, supplemented or otherwise modified from time to time
“Compliance Advisor”	Somerley Capital Limited
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules

DEFINITIONS

“connected transaction(s)”	has the meaning ascribed thereto under the Listing Rules
“Controlling Shareholders”	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Dr. Shen and his spouse, Ms. Jin Jie (金潔), for further details of which, please refer to the section headed “Relationship with our Controlling Shareholders”
“core connected person”	has the meaning ascribed thereto under the Listing Rule
“Core Product(s)”	has the meaning ascribed thereto in Chapter 18A of the Listing Rules; for the purpose of this document, our Core Products refer to VV116 (RSV indication), TPN171(ED indication) and LV232
“CSDC”	China Securities Depository and Clearing Co., Ltd. (中國證券登記結算有限責任公司)
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會), a regulatory body responsible for the supervision and regulation of the PRC national securities markets
“Director(s)” or “our Director(s)”	the director(s) of our Company, including all executive, non-executive and independent non-executive directors
“Dr. Shen”	Dr. Shen Jingshan (沈敬山), one of our founders and Controlling Shareholders
“Dr. Tian”	Dr. Tian Guanghui (田廣輝), one of our founders, chairman of the Board, executive Director, chief executive officer and general manager of our Company
“EIT”	enterprise income tax
“EIT Law”	the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time
“Employee Incentive Scheme”	the employee incentive scheme of our Company which was approved on January 13, 2025
“Employee Incentive Platform”	Suzhou Hesheng, the employee incentive platform under Employee Incentive Scheme

DEFINITIONS

“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the Government of Hong Kong
“FDA”	the United States Food and Drug Administration
“FIL”	Foreign Investment Law of the PRC (《中華人民共和國外商投資法》)

[REDACTED]

“Group”, “our Group”, “our”, “we” or “us”	our Company and all of our subsidiaries or, where the context so requires, in respect of the period before our Company became the holding company of its present subsidiaries, the businesses operated by such subsidiaries or their predecessors (as the case may be)
“Guide for New Listing Applicants”	the Guide for New Listing Applicants as published by the Stock Exchange in December 2023 and amended from time to time
“H Share(s)”	overseas [REDACTED] foreign share(s) in our ordinary share capital, with nominal value of RMB1.00 each in the share capital of our Company, which are to be [REDACTED] for and traded in HK dollars, and for which an application has been made for [REDACTED] and permission to trade on the [REDACTED]

[REDACTED]

“HKFRS”	Hong Kong Financial Reporting Standard
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DEFINITIONS

[REDACTED]

“Hong Kong” or “HK” the Hong Kong Special Administrative Region of the PRC

“Hong Kong dollars,” “HK dollars” or “HK\$” Hong Kong dollars, the lawful currency of Hong Kong

[REDACTED]

DEFINITIONS

[REDACTED]

“IASB”	International Accounting Standards Board
“IFRS”	the International Financial Reporting Standards as issued by the IASB, which comprise the IFRS Accounting Standards, International Accounting Standards, Interpretations developed by the IFRS Interpretations Committee or its predecessor body, the Standing Interpretations Committee
“Independent Third Party(ies)”	an individual or a company which, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is not a connected person of the Company within the meaning of the Listing Rules

DEFINITIONS

[REDACTED]

“Junshi Biosciences” Shanghai Junshi Biosciences Co., Ltd (上海君實生物醫藥科技股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 688180.SH) and the Stock Exchange (stock code: 1877.HK), and where the context so requires, together with its subsidiaries

“Latest Practicable Date” January 20, 2025, being the latest practicable date for the purpose of ascertaining certain information in this document prior to its publication

“Lianyungang Facility” our manufacturing facility located in Lianyungang, Jiangsu Province, see “Business — Manufacturing — Manufacturing Facility”

[REDACTED]

“Listing Committee” the Listing Committee of the Stock Exchange

DEFINITIONS

[REDACTED]

“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange, which is independent from and operated in parallel with the GEM of the Stock Exchange
“MOF”	Ministry of Finance of the PRC (中華人民共和國財政部)
“MOFCOM” or “Ministry of Commerce”	the Ministry of Commerce of the PRC (中華人民共和國商務部) (formerly known as the Ministry of Foreign Trade and Economic Cooperation of the PRC (中華人民共和國對外貿易經濟合作部))
“Nantong Hefeng”	Nantong Hefeng Lianwang Pharmaceutical Technology Co., Ltd. (南通和風連旺醫藥科技有限公司), a limited liability company established under the laws of PRC on October 10, 2020, acquired by and being a subsidiary of our Company
“NDRC”	the National Development and Reform Commission (中華人民共和國國家發展和改革委員會)
“NIPA”	the National Intellectual Property Administration of the PRC (中華人民共和國國家知識產權局)
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
“Nomination Committee”	nomination Committee of the Board
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

DEFINITIONS

[REDACTED]

“Overseas Listing Trial Measures”	Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) released by the CSRC on February 17, 2023 and took effect on March 31, 2023
“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC GAAP”	generally accepted accounting principles in the PRC
“PRC Legal Advisors”	JunHe LLP, the legal advisors to the Company as to the laws of the PRC

DEFINITIONS

“PRC Securities Law”	the Securities Law of the PRC (《中華人民共和國證券法》), as enacted by the 6th meeting of the 9th Standing Committee of the NPC on December 29, 1998 and became effective on July 1, 1999, as amended, supplemented or otherwise modified from time to time
“Pre-[REDACTED] Investment(s)”	the pre-[REDACTED] investment(s) in the Company undertaken by the Pre-[REDACTED] Investor(s), details of which are set out in the section headed “History, Development and Corporate Structure — Pre-[REDACTED] Investments” in this document
“Pre-[REDACTED] Investor(s)”	the investor(s) of Pre-[REDACTED] Investment(s)

[REDACTED]

“Qingdao Antai”	Qingdao Antai Rushan Biopharmaceutical Co., Ltd. (青島安泰如山生物醫藥有限公司), a limited liability company established under the laws of PRC on April 28, 2024, being a subsidiary of our Company
“Qingdao Facility”	our manufacturing facility under construction in Qingdao, Shandong Province, see “Business — Manufacturing — Expansion Plan”
“R&D”	research and development
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration and Appraisal Committee”	remuneration and appraisal Committee of the Board
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAMR”	State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)

DEFINITIONS

“Securities and Futures Ordinance” or “SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“SFC”	the Securities and Futures Commission of Hong Kong
“Shandong Topharman”	Shandong Topharman Pharmaceutical Co., Ltd. (山東特珉曼藥業有限公司), a limited liability company established under the laws of PRC on November 13, 2004, which is owned as to 96.00% and 4.00% by Dr. Shen and his spouse, Ms. Jin Jie (金潔)
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising Unlisted Shares and H Shares
“Shareholder(s)”	holder(s) of our Share(s)

[REDACTED]

“Sole Sponsor”	CITIC Securities (Hong Kong) Limited
“Sophisticated Investor(s)”	has the meaning ascribed to it under the Chapter 2.3 of the Listing Guide

[REDACTED]

“STA”	State Taxation Administration (中華人民共和國國家稅務總局)
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[REDACTED]

“State Council”	the State Council of the PRC (中華人民共和國國務院)
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DEFINITIONS

“Stock Exchange” or “Hong Kong Stock Exchange”	The Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“subsidiary(ies)”	has the meaning ascribed thereto under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	supervisor(s) of our Company
“Supervisory Committee”	the supervisory Committee of our Company
“Suzhou Hesheng”	Suzhou Hesheng Enterprise Management Consulting Partnership Enterprise (Limited Partnership) (蘇州合升企業管理諮詢合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on June 22, 2021 and our Employee Incentive Platform
“Takeovers Code”	the Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Topharman Shanghai”	Topharman Shanghai Co., Ltd. (上海特化醫藥科技有限公司), a limited liability company established under the laws of PRC on March 8, 2000, which is owned as to 99.00% by Dr. Shen
“Track Record Period”	the year ended December 31, 2023 and the nine months ended September 30, 2024
“U.S. dollars,” “US\$” or “USD”	United States dollars, the lawful currency of the United States
“U.S. Securities Act”	the United States Securities Act of 1933, as amended and supplemented or otherwise modified from time to time, and the rules and regulations promulgated thereunder

[REDACTED]

DEFINITIONS

“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“Unlisted Share(s)”	ordinary share(s) issued by our Company, with a nominal value of RMB1.00 each, which is/are not listed on any stock exchange
“VAT”	value added tax
“Vigonvita Lianyungang”	Vigonvita (Lianyungang) Pharmaceutical Co., Ltd. (旺山旺水(連雲港)製藥有限公司), a limited liability company established under the laws of PRC on December 6, 2019, being a wholly-own subsidiary of our Company
“Vigonvita Shanghai”	Vigonvita (Shanghai) Biopharmaceutical Co., Ltd. (旺山旺水(上海)生物醫藥有限公司), a limited liability company established under the laws of PRC on August 19, 2022, being a wholly-own subsidiary of our Company
“Vigonvita Tashkent”	Vigonvita Tashkent LLC, a limited liability company incorporated under the laws of the Republic of Uzbekistan on May 12, 2021, being a wholly-own subsidiary of our Company

[REDACTED]

“Yingjiu Health”	Yingjiu Health Consulting (Suzhou) Co., Ltd. (英久健康諮詢(蘇州)有限公司), a limited liability company established under the laws of PRC on December 6, 2023, being a wholly-own subsidiary of our Company
“%”	per cent

For the purpose of this document, references to “provinces” of China include provinces, municipalities under direct administration of the central government and provincial-level autonomous regions.

GLOSSARY OF TECHNICAL TERMS

“5-hydroxytryptamine 3 receptor” or “5-HT ₃ receptor”	a member of the Cys-loop superfamily of ligand-gated ion channels (LGICs). This ion channel is cation-selective and mediates neuronal depolarization and excitation within the central and peripheral nervous systems
“active pharmaceutical ingredient” or “API”	the substance in a pharmaceutical product that is biologically active
“adverse events” or “AEs”	any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“adverse reaction”, “adverse drug reaction” or “ADR”	unintended, harmful events attributed to the use of medicines
“ANDA”	abbreviated new drug application
“antagonist”	a type of drug that blocks or decreases a biological response by binding to and blocking a receptor or a ligand rather than activating it
“antidepressant”	a drug used to prevent or treat clinical depression
“antiepileptic”	a type of drug that is used to prevent or treat seizures or convulsions by controlling abnormal electrical activity in the brain
“antipsychotic”	a class of psychotropic medication primarily used to manage psychosis (including delusions, hallucinations, paranoia or disordered thought), principally in schizophrenia but also in a range of other psychotic disorders. They are also the mainstay, together with mood stabilizers, in the treatment of bipolar disorder and are used as adjuncts in the treatment of treatment-resistant major depressive disorder
“benign prostatic hyperplasia” or “BPH”	a noncancerous increase in size of the prostate gland. Symptoms may include frequent urination, trouble starting to urinate, weak stream, inability to urinate, or loss of bladder control

GLOSSARY OF TECHNICAL TERMS

“bioavailability”	the fraction of an administered dose of drug that reaches systemic circulation, which is one of the principal pharmacokinetic properties of drugs
“blood-brain barrier” or “BBB”	a highly selective semipermeable border of endothelial cells that regulates the transfer of solutes and chemicals between the circulatory system and the central nervous system, thus protecting the brain from harmful or unwanted substances in the blood
“brexpiprazole”	an atypical antipsychotic medication used for the treatment of major depressive disorder, schizophrenia, and agitation associated with dementia due to Alzheimer’s disease
“CAGR”	compound annual growth rate, the rate of return that would be required for an investment to grow from its beginning balance to its ending balance, assuming the profits were reinvested at the end of each year of the investment’s lifespan
“CDE”	Center for Drug Evaluation, a division of the NMPA
“central nervous system” or “CNS”	part of the nervous system consisting primarily of the brain and spinal cord
“cGMP”	current good manufacturing practice
“CMC”	chemistry, manufacturing, and controls processes
“CMO(s)”	contract manufacturing organization(s), a company that serves other companies in the pharmaceutical industry on a contract basis to provide drug manufacturing services
“COVID-19”	coronavirus disease 2019, a disease caused by the SARS-CoV-2 coronavirus and designated as severe acute respiratory syndrome
“CRO(s)”	a contract research organization, who provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CSO(s)”	contract sales organization(s)

GLOSSARY OF TECHNICAL TERMS

“cytomegalovirus” or “CMV”	a genus of viruses in the order Herpesvirales, in the family Herpesviridae, in the subfamily Betaherpesvirinae. They can infect virtually any organ of the human body, causing flu-like symptoms in healthy individuals, while leading to more serious conditions in vulnerable populations
“dapoxetine”	a selective serotonin reuptake inhibitor (SSRI) used for the treatment of premature ejaculation (PE) in men ages 18 to 64 years old
“DAT”	dopamine transporter, a membrane-spanning protein coded for in humans by the SLC6A3 gene (also known as DAT1), that pumps the neurotransmitter dopamine out of the synaptic cleft back into cytosol, in which other transporters sequester the dopamine into vesicles for storage and later release
“depressive disorder” or “depression”	a common mental disorder, involving a depressed mood or loss of pleasure or interest in activities for long periods of time
“DNA”	deoxyribonucleic acid, a self-replicating material which is present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information
“electromyography” or “EMG”	a technique for evaluating and recording the electrical activity produced by skeletal muscles
“Emergency Use Authorizations”	authority granted to the FDA during a public health emergency to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives
“enzyme”	a biological macromolecule that acts as a catalyst
“epilepsy”	a group of non-communicable neurological disorders characterized by recurrent epileptic seizures

GLOSSARY OF TECHNICAL TERMS

“erectile dysfunction” or “ED”	a form of sexual dysfunction in males characterized by the persistent or recurring inability to achieve or maintain a penile erection with sufficient rigidity and duration for satisfactory sexual activity
“first-in-class”	drugs that use a new and unique mechanism of action for treating a medical condition
“first-line treatment” or “1L treatment”	the initial, or first treatment recommended for a disease or illness
“GBD2021”	Global Burden of Disease Study 2021, a study that estimated the burden of diseases, injuries, and risk factors for 204 countries and territories and selected subnational locations
“GCP”	Good Clinical Practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“generic drug(s)” or “generic product(s)”	a pharmaceutical that contains the same active ingredients as an original formulation and is comparable in dosage form, strength, quality, performance and intended use
“GFA”	gross floor area
“GLP”	Good Laboratory Practice
“GMP”	Good Manufacturing Practice, guidelines and regulations from time to time issued pursuant to the PRC Drug Administration Law (《中華人民共和國藥品管理法》) as part of quality assurance which aims to minimize the risks of contamination, cross contamination, confusion and errors during the manufacture process of pharmaceutical products and to ensure that pharmaceutical products subject to these guidelines and regulations are consistently produced and controlled in conformity to quality and standards appropriate for their intended use
“gold standard”	the best available therapy, product or treatment
“Grade III hospitals”	tertiary hospitals that provide high-level specialized medical services and undertake advanced teaching and scientific research tasks

GLOSSARY OF TECHNICAL TERMS

“GSP”	Good Supply Practice, guidelines and regulations from time to time issued pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) to provide quality assurance and ensure that pharmaceutical distribution enterprises distribute pharmaceutical products in compliance with the guidelines and regulations
“hypoactive sexual desire disorder” or “HSDD”	type of mental and physical sexual dysfunction in women, which is characterized as a lack or absence of sexual fantasies and desire for sexual activity
“IIEF-EF”	International Index of Erectile Function erectile function domain score
“ <i>in vitro</i> ”	“in glass” in Latin, <i>in vitro</i> studies are conducted outside of a living organism in a laboratory environment using test tubes, petri dishes, etc. using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
“ <i>in vivo</i> ”	“within the living” in Latin, <i>in vivo</i> studies are those in which the effects of various biological entities are tested on whole, living organisms as opposed to a partial or dead organism, or those done <i>in vitro</i>
“IND”	investigational new drug, an application and approval process required before drug candidates may commence clinical trials
“inflammation”	a protective biological response to injury or infection, which serves to destroy, dilute, or wall off both the injurious agent and the injured tissues
“inhibitor”	a chemical or substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
“ISO”	International Organization for Standardization
“KOLs”	key opinion leaders

GLOSSARY OF TECHNICAL TERMS

“letermovir”	an antiviral drug for the treatment of CMV infections and has been tested in CMV infected patients with allogeneic stem cell transplants and may also be useful for other patients with a compromised immune system such as those with organ transplants or HIV infections
“metabolite”	an intermediate or end product of metabolism
“Model-Informed Drug Development” or “MIDD”	an approach that involves developing and applying exposure-based biological and statistical models derived from preclinical and clinical data sources to inform drug development or regulatory decision-making
“monoclonal antibodies”	antibodies generated by identical immune cells that are all clones of the unique parent cell
“mortality”	death rate, varying by such parameters as age, gender and health
“NDA”	new drug application
“nerve”	a cordlike structure composed of axon that conduct sensory and motor impulses between the brain and spinal cord and other areas of the body
“NET”	norepinephrine transporter, a protein responsible for the reuptake of norepinephrine into presynaptic nerve terminals, which is mainly responsible for the sodium-chloride-dependent reuptake of extracellular norepinephrine
“neuron(s)”	an excitable cell type that fires and transmits electric signals called action potentials across neural network
“neuropsychiatry”	a branch of medicine that deals with psychiatry as it relates to neurology, in an effort to understand and attribute behavior to the interaction of neurobiology and social psychology factors
“neurotransmitter”	a signaling molecule that is released from synaptic vesicles at the end of a nerve fiber by the arrival of a nerve impulse and, by diffusing across the synapse or junction, causes the transfer of the impulse to another nerve fiber, a muscle fiber or some other structure

GLOSSARY OF TECHNICAL TERMS

“neutralizing antibodies”	an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically
“noradrenergic and specific serotonergic antidepressant” or “NaSSA”	a class of antidepressants that bind to and inhibit both noradrenaline α 2-autoreceptors and noradrenaline α 2-heteroreceptors, exerting a dual mechanism of action that increases the concentration of 5-HT and noradrenaline in the synaptic cleft to within the normal range
“NRDL”	China’s National Reimbursement Drug List, also known as Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), which was published by Ministry of Human Resources and Social Security of the People’s Republic of China (中華人民共和國人力資源和社會保障部) on November 27, 2009 and amended from time to time. The latest version of NRDL was jointly published by National Healthcare Security Administration (國家醫療保障局) and Ministry of Human Resources and Social Security of the People’s Republic of China in 2024 and came into force on November 27, 2024
“NSAID”	nonsteroidal anti-inflammatory drugs
“nucleoside”	a compound consisting of a purine or pyrimidine base linked to a pentose sugar, especially ribose or deoxyribose
“PCC”	preclinical candidate
“PCT”	the Patent Cooperation Treaty
“PDE5”	type-5 phosphodiesterase, a multidomain protein that functions as a dimer to hydrolyze cyclic guanosine monophosphate
“pharmacodynamics” or “PD”	the study of the biochemical and physiologic effects of drugs, which include those manifested within animals (including humans), microorganisms, or combinations of organisms

GLOSSARY OF TECHNICAL TERMS

“pharmacokinetics” or “PK”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“pharmacology”	the science that deals with the origin, nature, chemistry, effects, and uses of drugs, including pharmacognosy, pharmacokinetics, pharmacodynamics, pharmacotherapeutics and toxicology
“phase I clinical trial(s)”	studies in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“phase II clinical trial(s)”	phase II clinical trials test the new drug candidate on a larger group of patients, to gather information about whether it works and how well it works in the short-term
“phase III clinical trial(s)”	phase III clinical trials are for a new drug candidate that has already passed phases I and II which test the new drug candidate in larger groups of patients, and compare the new drug candidate against an existing treatment or a placebo to see if it works better in practice and if it has important side effects
“placebo”	a substance or treatment with no active therapeutic effect, commonly used in clinical trials as the administered substance for the control group
“PMDA”	Pharmaceuticals and Medical Devices Agency, an Independent Administrative Institution responsible for ensuring the safety, efficacy and quality of pharmaceuticals and medical devices in Japan
“pneumonia”	an infection of one or more lungs which is usually caused by bacteria, viruses or fungi
“preclinical studies”	pre-clinical studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials

GLOSSARY OF TECHNICAL TERMS

“premature ejaculation” or “PE”	a male sexual dysfunction that occurs when a male expels semen soon after beginning sexual activity, and with minimal penile stimulation
“PUD”	peptic ulcer disease
“pulmonary arterial hypertension” or “PAH”	a syndrome in which the blood pressure in the pulmonary arteries and pulmonary arterioles (the blood vessels located proximal to the capillary bed, the site of oxygen exchange in the lungs) is elevated
“rebamipide”	an amino acid derivative of 2-(1H)-quinolinone, is used for mucosal protection, healing of gastroduodenal ulcers, and treatment of gastritis
“Remdesivir”	a broad-spectrum antiviral medication developed by the biopharmaceutical company Gilead Sciences
“RNA”	a single-stranded molecule composed of four types of smaller molecules called ribonucleotide bases: adenine (A), cytosine (C), guanine (G), and uracil (U)
“RNA-dependent RNA polymerase” or “RdRp”	an enzyme that catalyzes the replication of RNA from an RNA template
“RSV”	respiratory syncytial virus, a contagious virus that causes infections of the respiratory tract
“SARS”	severe acute respiratory syndrome, a viral respiratory disease caused by a SARS-associated coronavirus
“SARS-CoV-2”	severe acute respiratory syndrome coronavirus 2, a novel coronavirus called severe acute respiratory syndrome coronavirus 2
“schizophrenia”	a mental disorder characterized variously by hallucinations (typically, hearing voices), delusions, disorganized thinking and behavior, and flat or inappropriate affect
“selective serotonin reuptake inhibitor” or “SSRI”	a class of antidepressants that increase levels of serotonin in the brain by preventing the reuptake of serotonin by nerves

GLOSSARY OF TECHNICAL TERMS

“serious adverse event” or “SAE”	any untoward medical occurrence in a patient during clinical trials that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect
“serious adverse reactions” or “SADRs”	harmful and unintended responses to drugs that can cause death, hospitalization, or other serious consequences
“serotonin and norepinephrine reuptake inhibitors” or “SNRI”	a family of antidepressants that inhibit the reuptake of both serotonin and norepinephrine
“serotonin transporter” or “5-HTT”	a protein that in humans is encoded by the SLC6A4 gene. It is a type of monoamine transporter protein that transports the neurotransmitter serotonin from the synaptic cleft back to the presynaptic neuron, in a process known as serotonin reuptake
“severe fever with thrombocytopenia syndrome virus” or “SFTSV”	a tick-borne virus in the genus Bandavirus in the family Phenuiviridae, order Bunyavirales. Infection with SFTSV can trigger immune dysfunction, cytokine storms, endothelial damage, and, in severe cases, death due to bleeding or multiple organ failure
“small molecule”	a low molecular weight ($\leq 1,000$ daltons) organic compound that may regulate a biological process
“sq.m.”	square meter, a unit of area
“translational medicine”	an area of research that aims to improve human health by translating basic science discoveries into applied science in medical practice
“treatment-related adverse event” or “TRAE”	an event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state
“voltage-gated ion channels”	a class of transmembrane proteins that form ion channels that are activated by changes in a cell’s electrical membrane potential near the channel
“WHO”	World Health Organization

FORWARD-LOOKING STATEMENTS

We have included in this document forward-looking statements. Statements that are not historical facts, including statements about our intentions, beliefs, expectations or predictions for the future, are forward-looking statements.

This document contains certain forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words "aim," "anticipate," "believe," "could," "estimate," "expect," "going forward," "intend," "may," "might," "ought to," "plan," "potential," "predict," "project," "seek," "should," "will," "would" and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change.

These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing our Company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our operations and business prospects;
- our financial conditions and operating results and performance;
- future developments, trends and conditions in the industry and markets in which we operate;
- our strategies, plans, objectives and goals and our ability to successfully implement these strategies, plans, objectives and goals;
- general economic, political and business conditions in the markets in which we operate;
- changes to regulatory and operating conditions in the industry and markets in which we operate;
- our ability to continue to maintain our position in the industry;
- our ability to attract customers and build our brand image;
- our ability to control or reduce costs;
- our ability to identify and integrate suitable acquisition targets;

FORWARD-LOOKING STATEMENTS

- our dividend policy;
- our capital expenditure plans;
- the amount and nature of, and potential for, future development of our business;
- capital market developments;
- our future debt levels and capital needs;
- the competitive environment of the industry and markets in which we operate;
- our ability to attract and retain senior management and key employees;
- the actions and developments of our competitors;
- certain statements in “Business” and “Financial Information” in this document with respect to trends in prices, operations, margins, overall market trends, and risk management;
- change of volatility in interest rates, equity prices, volumes, operations, margins, risk management and overall market trends; and
- other statements in this document that are not historical facts.

Subject to the requirements of applicable laws, rules and regulations, we do not have any and undertake no obligation to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise. As a result of these and other risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect or at all. Accordingly, the forward-looking statements are not a guarantee of future performance and you should not place undue reliance on any forward-looking information. Moreover, the inclusion of forward-looking statements should not be regarded as representations by us that our plans and objectives will be achieved or realized. All forward-looking statements in this document are qualified by reference to the cautionary statements in this section.

In this document, statements of or references to our intentions or those of the Directors are made as of the date of this document. Any such information may change in light of future developments.

RISK FACTORS

An [REDACTED] in our H Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in our H Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In any such case, the [REDACTED] of our H Shares could decline, and you may lose substantial or all of your [REDACTED].

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-looking Statements.”

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUGS AND DRUG CANDIDATES

Our business and financial prospects depend substantially on the success of our clinical stage and preclinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.

Our revenue and profitability are substantially dependent on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully manufacture and commercialize our drug candidates. As of the Latest Practicable Date, we had built a robust pipeline of innovative assets centered around our strategically focused three therapeutic areas, consisting of two in commercial or near-commercial stage, four in clinical stage and three in preclinical stage. We have invested a significant portion of our efforts and capital resources in the development of our innovative drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future.

We cannot guarantee that we will be able to obtain regulatory approvals for our drug candidates in a timely manner, or at all. The success of our drug candidates will depend on several factors, including but not limited to:

- completion of preclinical studies as well as completion of clinical trials, including successful and timely enrollment of patients;
- favorable safety and efficacy data from our clinical trials and other studies;

RISK FACTORS

- obtaining sufficient supplies of competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- establishing sufficient commercial manufacturing capabilities;
- the capabilities and competence of our collaboration partners and the success of clinical trials conducted by, or jointly with, our collaboration partner;
- the performance by CROs or other third parties we may retain to conduct clinical trials and preclinical studies of their duties to us in a manner that complies with our protocols and applicable laws without damaging or compromising the integrity of the resulting data;
- obtaining, maintaining, and enforcing patent, trademark, trade secret, and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defend against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- receipt of regulatory approvals from applicable regulatory authorities;
- successfully launching commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining favorable reimbursement from third-party payers for drugs, if and when approved;
- success of our products, particularly our Core Products which faces competition from several approved products and product candidates under development, in competing with these and other drug candidates and drugs; and
- continued acceptable safety profiles of our drug candidates following regulatory approvals.

If we do not achieve one or more of these in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for and commercializing our drug candidates, which would materially harm our business and may prevent us from generating sufficient revenues and cash flows to continue our operations.

RISK FACTORS

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts.

The global pharmaceutical industry is constantly evolving and in order to maintain our competitive position, we need to devote significant financial and other resources to our research and development activities to keep up with new technologies and methodologies. For example, we have made significant efforts to develop our proprietary technology platforms, which allow us to continuously develop a strong pipeline of drug candidates. In 2023 and the nine months ended September 30, 2023 and 2024, our research and development expenses were RMB131.3 million, RMB102.0 million and RMB100.5 million, respectively. We must continue to allocate significant amounts of human and capital resources to develop or acquire technologies that will enable us to improve the breadth and caliber of our clinical trials. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis.

As of the Latest Practicable Date, three of our drug candidates were in preclinical stage. See “Business — Innovative Drug Candidates.” Commencement of a clinical trial is subject to finalizing trial design based on ongoing discussions with the NMPA, the Center for Pharmaceutical Products Safety or other regulatory authorities. We cannot assure you as to when the clinical trials for our drug candidates in discovery and preclinical stages will begin, if at all.

As of the Latest Practicable Date, four of our drug candidates were in clinical stage. However, the successful completion of clinical trials is an essential requirement to obtain NDA or similar approvals from the NMPA, the Center for Pharmaceutical Products Safety, or other comparable regulatory authorities for each of our drug candidates and, ultimately, the commercialization of our drug candidates. Clinical trials, however, come with an expense, are challenging to plan and carry out, and can take years to finish with no guarantee of success. Failure can occur at any time or stage during the clinical development process, which would result in a material and adverse effect on our business, financial condition and results of operations.

RISK FACTORS

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approvals for the development and commercialization of our drug candidates, including but not limited to situations whereby:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated, or the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- we may not be able to reach agreements on acceptable terms with prospective third-party contractors and they may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our drug candidates for various reasons, including non-compliance with regulatory requirements, a finding of a lack of meaningful clinical responses, a finding that participants are being exposed to unacceptable health and safety risks or other unexpected characteristics;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated; and
- we may encounter various manufacturing issues, including inability to ensure that the supply and quality of our drug candidates and other materials necessary to conduct clinical trials of our drug candidates is sufficient and adequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all;
- obtain approval for proposed indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

RISK FACTORS

Delays in clinical trials or obtaining regulatory approvals may result in increases in our drug development costs. We cannot assure you whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant delays in clinical trials could also shorten any periods during which we have the right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do, which could impair our ability to commercialize our drug candidates and may have an adverse effect on our business and results of operations.

If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients in the clinical trials. We may fail or experience significant delays to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, the Center for Pharmaceutical Products Safety or similar regulatory authorities. In particular, we may face additional difficulties when enrolling patients who are infants and young children or patients with diseases with seasonal fluctuations or rare diseases. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials.

Patient enrollment for our clinical trials may be affected by many factors. For example, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' drug candidates. Other factors include:

- severity of the disease under investigation;
- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- the ability to obtain and maintain informed consents;
- the risk that enrolled patients will not complete a clinical trial;

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- clinicians’ and patients’ perceptions as to the potential advantages and risks of the candidate being studied compared to other available therapies, including any new products that may be approved for the indications we are investigating as well as any candidates under development;
- patient referral practices of physicians;
- our investigators’ or clinical trial sites’ efforts to screen and recruit eligible patients;
- proximity and availability of clinical trial sites for prospective patients; and
- epidemics.

Failure to enroll a sufficient number of patients in our clinical trials on a timely manner could prevent completion of our trials and adversely affect our ability to advance the development of our drug candidates.

We may allocate our limited resources to pursuing particular drug candidates or indications and fail to capitalize on other drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success.

As we have limited financial and managerial resources, we focus our product pipeline on drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Adverse events or undesirable side effects caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, or result in other significant negative consequences.

AEs and undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our drug candidates, a delay or denial of regulatory approval by the NMPA, the Center for Pharmaceutical Products Safety or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. Results of trials conducted by us or by our collaborating partners with respect to our licensed drug candidate could reveal a high and unacceptable severity or

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prevalence of certain AEs. In such an event, such trials could be suspended or terminated, and the NMPA, the Center for Pharmaceutical Products Safety or other comparable regulatory authorities could order us or our collaborating partners, as applicable, to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. AEs related to our drug candidates may also affect patient enrollment or the ability of enrolled patients to complete the trial, and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Additionally, any AEs or undesirable side effects caused by our drug candidates after they receive regulatory approval may lead to potentially significant negative consequences which include, but are not limited to, the following:

- regulatory authorities may withdraw approvals or revoke licenses of our approved drug candidates;
- we, or our collaborating partners, as applicable, may have to suspend marketing of our approved drug candidates;
- regulatory authorities may require additional warnings on the label of an approved drug candidate or impose other limitations on an approved drug candidate;
- the NMPA, the Center for Pharmaceutical Products Safety or a comparable regulatory authority may require the establishment of a Risk Evaluation and Mitigation Strategy, or other similar plans, which may restrict distribution of our approved drug candidates and impose burdensome implementation requirements on us, among other risk mitigation tools;
- we, or our collaborating partners, as applicable, may be required to change the way the approved drug candidate is administered, or conduct post-marketing studies;
- we could be subject to litigation proceedings and held liable for harm caused to patients exposed to or taking our approved drug candidates, who may suffer from adverse events related to the treatment; and
- our reputation may suffer.

Any of the abovementioned events could prevent us or our collaborating partners, as applicable, from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, financial condition, results of operations and prospects.

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Findings and results of pre-clinical studies or early clinical trials may not be predictive of future trial results.

The findings and results of preclinical studies and early clinical trials and may not be predictive of the success of later phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily predict successful final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. As drug candidates are developed through preclinical to early- to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives.

In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including ethnical and genetic differences, patient adherence to the dosing regimen and other trial protocol elements, the rate of dropout among clinical trial participants, and other compounding factors, such as other medications or pre-existing medical conditions. In the case of any trials we conduct, results may differ from earlier trials due to, among other things, the larger number of clinical trial sites, additional countries and languages involved in such trials, the different conductors of the trials, different clinical trial standards required in different jurisdictions, different patient population, and different standard of care and pretreatment of patients before enrolling in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates and/or jeopardize our ability to commence commercialization of our drug candidates.

We may not be able to identify, discover or develop new drug candidates, or to identify or develop new indications for our drug candidates, or to expand or maintain our product pipeline.

Although we expect to focus a substantial amount of our efforts on the continued clinical testing, potential approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to identify, discover, develop or commercialize additional drug candidates, or to identify or develop new indications for our drug candidates. Some drug candidates are technically challenging to develop and manufacture. We may consider pursuing collaboration with third parties in the discovery and development of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results.

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Research programs to identify new drug candidates and to develop our drug candidates for additional indications require substantial technical, financial and human resources. Our research programs may initially show promising results in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including, without limitation, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential indications and/or new drug candidates; and
- our potential drug candidates may, after further study, be shown to have harmful side effects or may have other characteristics that may make the drug candidates unlikely to achieve desired efficacy, unmarketable or unlikely to receive marketing approval.

Accordingly, there can be no assurance that we will be able to identify new drug candidates or develop new indications for our drug candidates or to develop suitable potential drug candidates through internal research programs. We may invest efforts and resources in potential drug candidates or indication expansions that ultimately prove to be unsuccessful. Any of the foregoing events will have a material adverse effect on our business, results of operations and prospects.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the pharmaceutical industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the pharmaceutical industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our drug candidates, for which we manage and submit data to governmental authorities. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a patient, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or

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other data was wrongful or erroneous. The insurance coverage for clinical trials may prove to be inadequate or could cease to be available to us on acceptable terms, or at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on certain third parties, such as CROs, to monitor and manage data for some of our ongoing preclinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical studies and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For a detailed discussion, please see “— Risks Relating to Our Reliance on Third Parties — We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.”

In conducting drug discovery, development and commercialization, we face potential liabilities, in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability claims as a result of the clinical trials of our drug candidates and commercialization of our drugs. For example, we may be sued if our drugs and drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws.

Liability claims may result in decreased demand for our approved drugs, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management’s time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals, or labeling, marketing or promotional restrictions, loss of revenue, exhaustion of any available insurance and our capital resources, the inability to commercialize any approved drug candidate, and a decline in the [REDACTED] of our H Shares.

To cover any such liability claims arising from clinical studies, we purchase clinical trial liability insurance to cover adverse events in our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims are brought against us for

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uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO SALES AND DISTRIBUTION AND COMMERCIALIZATION OF OUR DRUGS AND DRUG CANDIDATES

We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our revenue and profitability and our ability to successfully commercialize our drug candidates.

The pharmaceutical industry is subject to fierce competition and rapid and significant technological advancements. We face competition with respect to our current drugs and drug candidates from existing products and product candidates under development in the therapeutic areas that we focus on, and we will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are developing our drug candidates in competition with a number of companies that have commercialized, are in the process of commercializing, or are pursuing the development of drugs for the same targets and/or indications as ours. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Even if successfully developed and subsequently approved by the NMPA, the Center for Pharmaceutical Products Safety or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Many of our competitors against which we are competing or against which we may compete may have substantially greater financial, technical and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies and institutions. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better acceptance in the markets in which we operate or have established a competitive

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position. If any of our competitors obtains regulatory approvals for drugs that may compete with our Core Products or other drug candidates, we may lose our potential first-mover advantage for certain indications and result in negative impact on our financial performance.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring, or licensing products that are more effective or less costly than our drug candidates or any future drug products that we may develop, or achieve earlier patent protection, regulatory approvals, product commercialization, and market penetration than we do. Our competitors also may obtain approval from the NMPA, the Center for Pharmaceutical Products Safety or other regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may cause us to experience delay in obtaining regulatory approval for our drug candidates or render our drug candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our drug candidates.

Some of our products are generic pharmaceuticals, and they face strong competition from the originator drugs and other generic versions, which may be sold at lower prices and therefore exert pricing pressure on our products. In addition, other pharmaceutical companies may obtain the relevant production approvals to sell generic pharmaceutical products with similar formulation or production processes in China, which could subject us to additional competition and adversely affect our business and results of operations. If we fail to protect our products from competition and remain competitive, our revenue and profitability may be materially and adversely affected.

We have limited experience in the commercialization of drugs. If we are unable to maintain and expand an effective sales and distribution network for our drugs and future approved drug candidates, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our drugs and future approved drug candidates, which could negatively affect our ability to effectively sell them and would materially and adversely affect our business, results of operations, financial condition and prospects.

We rely on our in-house sales and marketing team and engage third parties to market, promote and distribute our products. For details, see “Business — Marketing and Sales.” As we have just commenced commercial sales of VV116 in Uzbekistan in 2023 and dapoxetine in China in 2024, respectively, we do not have a proven track record of successfully marketing or selling our products. We have limited experience in building a commercial team, conducting a comprehensive market analysis, or managing distributors and sales force for our drugs and future approved drug candidates.

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Sales efforts of pharmaceutical products necessitate our sales and marketing force to possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication abilities. However, there is no assurance that there will be a sufficient amount of competent sales professionals with the relevant disease knowledge and/or academic KOLs or doctor networks available in the market. As a result, if we are unable to effectively train our in-house sales representatives or monitor and evaluate their academic marketing performance, our sales and marketing may be less successful than desired. Moreover, our ability to attract, motivate and retain a sufficient number of qualified sales professionals is especially important because we primarily rely on our in-house sales force to market our products. As competition for experienced marketing, promotion and sales personnel is intense, we may be unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals. Consequentially, sales volume of our products may be adversely affected and we may be unable to expand our coverage of hospitals, pharmacies and other medical institutions or increase our market penetration as contemplated.

In addition, we plan to continue strengthening our cooperative relationship with hospitals, physicians and research institutions for enhancing our product awareness in the market. For example, we may perform regular visits in hospitals, collaborate with leading universities and research institutions, and cooperate with KOLs to conduct post-launch clinical studies to promote the market acceptance of our products. However, such promotional activities may not be as effective as we expected, or may be impeded by unanticipated events, which may cause a decline of our sales revenue, and have a material adverse effect on our business, financial condition and results of operations.

Moreover, as we cooperate with distributors to distribute our products and intend to continue engaging distributors to sell our products in the foreseeable future, our ability to maintain and grow our business depends on our ability to maintain and manage a sufficient number of distributors with an extensive sales network, which we could fail to achieve for several reasons. First, our distributors may be unable to maintain or expand their sales network, or otherwise encounter any difficulties in selling our products. Additionally, our distributors might elect not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons, such as price controls or other factors that substantially reduce the margins they can obtain through the resale of our products. Further, we may fail to find an appropriate group of distributors suitable for our products, or the costs of doing so are prohibitively high. Consequently, any disruption to our distribution network, including our failure to maintain relationships, form new relationships or renew our existing distribution agreements, could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, results of operations, financial condition and prospects.

There can be no assurance that we will be able to successfully develop and maintain in-house commercial capabilities or establish or maintain relationships with third-party partners to successfully commercialize any approved drug, and as a result, our ability to generate product sales revenue may be negatively affected.

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The size of the potential market for our current or future drugs and drug candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our current or future drug candidates may be smaller than our estimates.

Our projections of the number of patients who have the potential to benefit from treatment with our drugs and drug candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. In addition, the mutagenicity of RNA viruses leads to the ongoing emergence of new variants, which may negative impact the efficacy of our antiviral drugs. Therefore, the number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our drugs and drug candidates may be smaller than our estimates.

Our drugs and future approved drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for our drug candidates' commercial success.

Our drugs and future approved drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. In addition, physicians, patients and third-party payors may prefer other novel products to ours. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drugs and future approved drug candidates are approved;
- physicians, hospitals and patients' perception of our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of applicable regulatory authorities;
- limitations or warnings contained in the labeling approved by applicable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;

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- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance in the medical community, we will not be able to generate significant revenue. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies introduced that are more favorably received or more cost-effective. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

Our commercialization efforts to date have focused primarily on China. Our ability to enter overseas markets will depend, among other things, on our ability to navigate various regulatory regimes with which we do not have experience, which could delay or prevent the growth of our operations outside of China.

To date, our commercialization efforts have focused primarily on China. We have sold and expect to continue to expand our selling scale of our drugs and future approved drug candidates in Uzbekistan and other countries and regions. Our ability to strengthen our commercial capabilities and deepen our penetration in overseas markets will require considerable management attention and resources and is subject to the particular challenges of supporting a growing business in an environment of multiple languages, cultures, customs, legal systems, alternative dispute resolution systems, regulatory systems and commercial infrastructures. Entering new international markets will be expensive, our ability to successfully capture on market opportunities in any particular market is uncertain and the distraction of our senior management team could harm our business, financial condition and results of operations.

Sales of our drugs and future approved drug candidates outside of China are subject to overseas regulatory requirements that vary widely from country to country. Complying with overseas regulatory requirements, including obtaining registrations or marketing approvals, can be expensive and time-consuming, and we may not receive regulatory authorizations, clearances or approvals in each country in which we may plan to market our drugs or future approved drug candidates or we may be unable to do so on a timely basis. The time required to obtain registrations or marketing approvals, if required by other countries, may be longer than that required for NMPA clearance, authorization, or approval in China, and requirements for such registrations and marketing authorizations may significantly differ from NMPA requirements. If we extend the indications of our drugs or future approved drug candidates, we

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may need to apply for additional regulatory approvals before we are permitted to commercialize the relevant drugs for the extended indications. In addition, we may not continue to meet the quality and safety standards required to maintain the approvals that we have received. If we are unable to maintain our approvals in a particular country, we may no longer be able to sell the drugs or future approved drug candidates in that country. A failure or delay in obtaining registration or marketing approvals in one country may have a negative effect on the regulatory process in others.

Doing business internationally also involves a number of additional risks, including data security risks, intellectual property protection, financial risks, and other force majeure factors. These risks and uncertainties may impact our ability to enter overseas markets or maintain our operation in overseas markets, which could delay or prevent the growth of our operations overseas, and have a material adverse effect on our business, prospects, results of operations and financial condition.

Our drug candidates may not be covered by insurance or reimbursement programs or may become subject to unfavorable insurance policies or reimbursement practices, either of which could harm our business, and we may be subject to unfavorable pricing regulations, which could make it difficult for us to sell our drugs profitably.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction. We intend to seek approval to market our drug candidates in China and in other jurisdictions. In general, the pricing of drugs is subject to governmental oversight and regulation, which can take considerable time even after obtaining regulatory approval. Thus, our ability to commercialize any approved drug candidates successfully will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In China, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security, together with other government authorities, regularly review the inclusion or removal of drugs from the NRDL. The NRDL determines a pharmaceutical product’s reimbursement standards for program participants under the National Medical Insurance Program. Under the National Medical Insurance Program, patients are entitled to full or partial reimbursement of costs for pharmaceutical products listed in the NRDL. A pharmaceutical product’s inclusion in or exclusion from the NRDL and its tier under the NRDL will significantly affect the demand for such product in China. There is no assurance that any of our future approved drug candidates will be included in the NRDL. The inclusion of pharmaceutical products by relevant authorities into the NRDL is based on a variety of factors, including efficacy, safety and price. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which may make our products less competitive. Patients may choose

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other drugs with similar efficiency but lower prices which have been included in the NRDL. Additionally, even if the Ministry of Human Resources and Social Security of China or any of its local counterparts were to accept our application for the inclusion of products in the NRDL, our potential revenue from the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL.

Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drug candidates. Patients are unlikely to use any of our future approved drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs.

Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any approved drug candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidates that we commercialize. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and reimbursement coverage may be more limited than the approved indications of the drug candidates by the NMPA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers. Our inability to promptly obtain reimbursement coverage at profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

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If we are unable to succeed in tender processes to sell our future approved drug candidates to PRC public hospitals and other medical institutions, we may lose market share and our revenue and profitability could be materially and adversely affected.

We expect to sell a portion of our future approved drug candidates, through distributors, to public hospitals and other medical institutions owned or controlled by government authorities in China. Each of these institutions must generally procure pharmaceuticals through a centralized pharmaceutical procurement platform organized by local government authorities, and source substantially all of their pharmaceuticals through a centralized tender process. We and our competitors will submit bids in such tender process to supply pharmaceutical products to these institutions at specified prices. The relevant government authorities evaluate these bids based on a number of criteria, such as bidding price, product quality, clinical effectiveness and reputation and after-sales service of the manufacturers. If we succeed in the tender process, the relevant products will be sold to the public hospitals and other medical institutions at the bid prices through our distributors, which is the primary determinant of the prices at which we sell these future approved drug candidates to our distributors.

We may fail to win bids in a tender process due to various factors, including reduced demand for the relevant future approved drug candidates, uncompetitive bidding price, failure to meet certain quality requirements, insufficient service quality to meet tender requirements, perception that our future approved drug candidates are less clinically effective than competing products or our service or other aspects of our operations are less competitive. If our future approved drug candidates are not selected in the tender processes in one or more regions, we will be unable to sell these future approved drug candidates to the public hospitals and other medical institutions in those regions, and our market share, revenue and profitability could be adversely affected.

The tender processes can also create pricing pressure among substitute products or products that are perceived to be substitute products. Our sales volumes and profitability depend on our ability to successfully differentiate our future approved drug candidates and price our bids in a manner that enables us to succeed in the centralized tender processes without compromising our profitability. If we are unable to differentiate our future approved drug candidates or are otherwise not successful in winning bids in the centralized tender processes at profitable levels, our market share, results of operations and profitability could be adversely affected.

Real or perceived incidents of severe side effects caused by our drugs or future drug products could materially and adversely affect our reputation and results of operations.

Our drugs and future approved drug candidates may cause undesirable or unintended side effects as a result of a number of factors, many of which are outside our control. These factors include potential side effects not revealed in clinical testing, unusual but severe side effects in isolated cases, defective products not detected by our quality management system, misuse of our drugs and future approved drug candidates by end-users.

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Further, our drugs and future approved drug candidates may be perceived to cause severe side effects if other pharmaceutical companies' products containing the same or similar active pharmaceutical ingredients, raw materials or delivery technologies as our products cause or are perceived to have caused severe side effects, or if regulators or international institutions determine that products containing the same or similar pharmaceutical ingredients as our products' could cause or lead to severe side effects. Our drugs and future approved drug candidates may also be perceived to cause severe side effects when a conclusive determination as to the cause of the severe side effects is not obtained or is unobtainable.

If our drugs and future approved drug candidates cause, or are perceived to cause, severe side effects, we may face a number of consequences, including, but not limited to: (i) injury or death of patients; (ii) a severe decrease in the demand for, and sales of, the relevant products; (iii) recall or withdrawal of the relevant products; (iv) revocation of regulatory approvals for the relevant products or the relevant production facilities; (v) damage to the brand name of our products and the reputation of our Company; (vi) stricter and more frequent regulatory inspections of our production facilities and products; (vii) removal of relevant drugs and future approved drug candidates from any medical insurance reimbursement lists; (viii) inability to participate in the centralized tender process; (ix) exposure to lawsuits and regulatory investigation relating to the relevant drugs and future approved drug candidates that result in liabilities, fines or penalties; and (x) breach of contract with our major customers. Such incidences may cause negative publicity and have material adverse impact on our business and results of operations.

Adverse drug reactions and negative results from off-label use of our drugs or future drug products could materially harm our business reputation, product brand name, financial condition and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use, i.e., prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. As such, there remains the risk that our drugs and future approved drug candidates are subject to off-label drug use and are prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities, rendering our drugs and future approved drug candidates less effective or entirely ineffective and causing adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including our share price. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

The illegal and/or counterfeit pharmaceutical products may reduce demand for our drugs and drug candidates, which could have a negative impact on our reputation and business.

The illegal import of similar or competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and

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profitability in China and other countries where we plan to commercialize our drug candidates. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our drugs and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers’ ability to import lower priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain pharmaceutical products distributed or sold in our target markets may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their usage or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The regulatory control and law enforcement system in relation to the counterfeit pharmaceutical products may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products in a timely manner, or at all. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved drug candidates. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences, which potentially exposes us to product liability claims, government investigations, and other disputes and negative consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaboration partners’ brand name(s).

Guidelines, recommendations and studies published by various organizations could disfavor our drug candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to our competitive drug candidates, could result in current or potential decreased use, sales of, and revenues from one or more of our drugs and drug candidates. Furthermore, our success depends in part on our and our partners’ ability to educate healthcare providers and patients about our drugs and drug candidates, and these education efforts could be rendered ineffective by, among other things, third-parties’ guidelines, recommendations or studies.

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RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We may not realize any or all benefits of collaboration, alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.

As an essential component of our research and development model, we have entered into a series of arrangements with leading domestic research institutions to acquire intellectual property rights of our Core Products. For more details, see “Business — Collaboration Arrangement.” Any of these relationships may require us to incur non-recurring and other charges or increase our near and long-term expenditures.

In addition, we have entered into, and may in the future enter into additional, co-development and licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drugs and drug candidates and any future drug candidates that we may develop. In particular, we have entered into out-licensing agreements in relation to VV116 with Junshi Biosciences. For more details, see “Business — Collaboration Arrangement.”

The abovementioned collaborations involving our drugs and drug candidates are subject to numerous risks, which may include the following:

- collaborations arrangements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the relevant drug candidate;
- collaboration partners may have significant discretion in determining the efforts and resources that they will apply under the collaboration arrangements;
- collaboration partners may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization projects based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;

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- collaboration partners could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- collaboration partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaboration partners may own or co-own intellectual property covering our drug candidates or future drugs that arise from the collaboration arrangements with them, in such cases we will not have exclusive right over such intellectual property; and
- disputes may arise between us and collaboration partners that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources.

For these and other reasons, we may not achieve the outcomes and synergies expected from the collaboration arrangements. The collaboration arrangements are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. We may face operational and financial risks including increase in near- and long-term expenditures, exposure to unknown liabilities, disruption of our business and diversion of our management’s time and attention. Even if we achieve the expected benefits, we may not be able to do so within the anticipated time frame.

As we expect to seek and form additional collaborations or strategic alliances in the future, we face significant competition in seeking appropriate strategic partners and the negotiation process can be time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may be required to relinquish some or all of the control over the future success of that drug candidate to the third party. The collaborators may also consider alternative drug candidates or technologies that may be available. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits. See also “— Risks Relating to Our Operations — We may engage in acquisitions or strategic partnerships in the future, which may increase our capital requirements, cause dilution for our Shareholders, cause us to incur debt or assume contingent liabilities or subject us to other risks.”

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If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into license and collaboration arrangements or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

As a result, we cannot be certain that, following a license and collaboration arrangement, we will achieve the revenue or net income that justifies such transaction or such other benefits that caused us to enter into the arrangement. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

We have worked with and plan to continue to work with third-party collaborators, such as CROs, to monitor and manage data for our ongoing preclinical and clinical programs. We work with these parties to execute our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our collaboration with the CROs and other third parties does not relieve us of our regulatory responsibilities.

We, our CROs for our clinical programs and our clinical investigators are required to comply with GCP, which are regulations and guidelines enforced by the NMPA and other comparable regulatory authorities for all of our drug candidates in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical studies, and clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

Our future revenues are dependent on our ability to work effectively with collaborators, such as CROs, to develop our drug candidates, including to obtain regulatory approval. Our arrangements with such collaborators will be critical to successfully bringing our drug candidates to market and commercializing them. We rely on third-party collaborators in various respects, including but not limited to undertaking research and development programs, conducting clinical trials, managing or assisting with the regulatory filings and approval process, and assisting with our commercialization efforts. We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product, which could materially and adversely affect our business, financial condition, cash flows and results of operations.

RISK FACTORS

We rely on third parties to satisfy a portion of our manufacturing needs and our business could be harmed if those third parties fail to provide us with sufficient quantities of the drug products or fail to do so at acceptable quality levels or prices.

During the Track Record Period and up to the Latest Practicable Date, we had worked with qualified CMOs to manufacture and test our drug candidates and products mainly under following circumstances: (i) before Lianyungang Facility was officially put into manufacturing; (ii) to manufacture certain drug candidates requiring manufacturing conditions that are not yet available in Lianyungang Facility. We expect to continue to rely on third party CMOs to satisfy a portion of our manufacturing needs. Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and cGMP-compliance inspections by the NMPA or other comparable regulatory authorities;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the regulatory authorities to ensure strict compliance with cGMP and other government regulations. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or human-made disasters.

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Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any future approved drug candidates for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.

While we rely on the distribution agreements and the policies and measures we have in place to manage our distributors, we cannot guarantee that we will be able to effectively manage our distributors, or that our distributors will abide by our agreements and policies. Specifically, if our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected: (i) failing to distribute our products in the manner we contemplate, impairing the effectiveness of our distribution network; (ii) breaching the distribution agreements or our policies and measures; (iii) failing to maintain the requisite licenses, permits or approvals, or failure to comply with applicable regulatory requirements; and (iv) violating any applicable anti-corruption, anti-bribery, competition or other laws and regulations. Any such actual or alleged violation or non-compliance by our distributors of the distribution agreements, our policies or any applicable laws and regulations could result in the erosion of our goodwill, expose us to liabilities, disrupt our distribution network and create an unfavorable public perception about the quality of our products.

RISKS RELATING TO MANUFACTURING OF OUR DRUG CANDIDATES

We have limited experience in manufacturing pharmaceutical products on a large commercial scale, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

As of the Latest Practicable date, we had one manufacturing facility located in Lianyungang, Jiangsu Province, with an aggregate GFA of approximately 51,955 sq.m., housing one workshop for small molecule drugs in oral solid dosage forms and one workshop for APIs. However, as we have only recently begun commercializing our products, our experience in manufacturing pharmaceutical products on a large commercial scale is limited. The manufacture of pharmaceutical products on a large commercial scale is a complex process requiring significant expertise and capital investment, in part due to strict regulatory requirements. The problems that may arise from the manufacturing process include but are not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;

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- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new manufacturing facilities or the expansion of our existing manufacturing facility;
- changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

If problems arise during the production process of certain future products, a batch or several related batches of such product may have to be discarded and cause production delays, cost increases, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the products are released to the market, recall and product liability costs may also be incurred.

We face additional manufacturing risks in relation to the CMOs that we engage from time to time. See “— Risks Relating to Our Reliance on Third Parties — We rely on third parties to satisfy a portion of our manufacturing needs and our business could be harmed if those third parties fail to provide us with sufficient quantities of the drug products or fail to do so at acceptable quality levels or prices.”

In addition, the quality of our drugs manufactured by us for commercial use in the future depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in manufacturing facility, the quality and reliability of equipment used, the quality of the operating staff and related training programs and our ability to ensure that our staff adhere to our quality control and quality assurance procedures. We cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance procedures could render our products unsuitable for use, or not in compliance with the relevant requirements of the cGMP and/or harm our market reputation and relationships with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

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Failure to obtain and maintain regulatory approvals for our planned manufacturing facility and damage to, destruction of or interruption of production at our existing and planned manufacturing facilities, could affect our development plans for our drug candidates or commercialization plans for our drugs or future approved drug candidates.

Lianyungang Facility commenced operations in June 2024. Considering the favorable support from local government, we are in the process of establishing Qingdao Facility in accordance with international GMP standards. With a GFA of approximately 11,272 sq.m., this new manufacturing facility is expected to support our efforts in exploring formulation and indication expansion opportunities. For details, see “Business — Manufacturing — Expansion Plan.” If we fail to obtain and maintain regulatory approvals for our Qingdao Facility, or encounter delays in the construction or obtaining approval of our Qingdao Facility, we may not be able to manufacture sufficient quantities of our drugs and future approved drug candidates in the future, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our Qingdao Facility and Lianyungang Facility could require us to raise additional funds from other sources.

Our manufacturing facilities, including both the existing Lianyungang Facility and the planned Qingdao Facility, are required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA or other comparable regulatory authorities to ensure compliance with cGMP regulations. Our manufacturing facilities are designed in compliance with the cGMP standards of NMPA. We cannot guarantee, however, that we will be able to adequately follow and document our adherence to such cGMP regulations or other regulatory requirements. Remediating deficiencies, if any, can be laborious, time consuming and costly. Failure to obtain and maintain such regulatory approvals may materially affect our R&D activities, and seriously delay the clinical trials and commercialization of our drugs and drug candidates, once approved. We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA or other comparable regulatory agency standards or specifications, maintaining consistent and acceptable production costs. We may also experience shortages of qualified personnel, raw materials or key contractors, or experience unexpected damage to our facilities or equipment. In these cases, we may be required to delay or suspend manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities. We may also be subject to sanctions for failure to comply with applicable regulations, including fines, injunctions, penalties, suspension of clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, suspension or withdrawal of approvals, supply disruptions, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could materially and adversely affect our business.

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In addition, if our manufacturing facilities or equipment are damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the manufacturing facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates or drugs in a timely manner could materially and adversely affect our business, financial condition and operating results.

We may not be able to meet the increasing demand for our drugs or future approved drug candidates by ensuring that we have adequate manufacturing capacity, to increase our production capacity as planned, to successfully manage our anticipated growth, or to precisely anticipate market demand.

To produce our increasing number of drugs and drug candidates, if approved, in the quantities that we believe will be required to meet anticipated market demand, we may need to increase, or "scale up," our production capacity over the initial level of production by constructing new manufacturing facilities and production lines. However, our ability to successfully implement our expansion plan for increasing production capacities is subject to a number of risks and uncertainties, including, but not limited to, the risk of construction delays and delays in equipment procurement, and our ability to timely recruit sufficient qualified staff to support the increase in our production capacity. If we are unable to do so, the cost of this scale up is not economically feasible for us, and we may not be able to product our future approved drug candidates in sufficient quantities to meet future demand. Moreover, our plans to increase our production capacities require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could adversely affect the return on our expenditure.

Furthermore, given the size of our existing and planned manufacturing facilities, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp up period, there may be significant changes in the macroeconomics of the pharmaceutical industry, including, among other things, market demand, product and supply pricing trends and customer preferences. Any adverse trends in these respects could result in operational inefficiency and unused capacity in our facilities.

RISK FACTORS

We procure certain raw materials from third-party suppliers for our manufacturing needs. Such supplies may not be available to us on acceptable terms or at all, and an increase in the market prices of such supplies may adversely affect our results of operations.

We procure certain raw materials from third-party suppliers in China for our manufacturing needs. We expect to continue to procure raw materials from third-party suppliers for the research, development and commercialization of our drug candidates. As we continue to develop and scale our manufacturing process and capacity, there is no assurance that we will be able to, at all times, procure the materials we need in adequate amount or on commercially reasonable terms, in a timely manner or at all. We might in the future encounter temporary difficulties in sourcing key raw materials as a result of health epidemics or outbreaks of contagious diseases as well as natural disasters, which could have a material impact on our business operations. For the risks associated with health epidemics or outbreaks of contagious diseases as well as natural disasters, see “— Risks Relating to Our Operations — We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control.” Moreover, we may not be able to continue to procure from any of our current suppliers due to other reasons, such as regulatory actions or requirements affecting certain supplier(s), adverse financial or other strategic developments experienced by certain supplier(s), labor disputes or shortages, unexpected demands, or quality issues. Failure to obtain sufficient supply of these materials could adversely affect our ability to satisfy demand for our drug candidates, which could adversely and materially affect our development process, future commercialization efforts and operating results.

Furthermore, as our manufacturing processes require substantial amounts of supplies, fluctuations in price of such supplies may directly and adversely impact on our profitability. During the Track Record Period, we had not experienced significant fluctuations in prices of supplies, and they are generally available and in sufficient quantity to meet our demands. However, we cannot assure you that this will continue to be the case in the future. The prices of supplies we use in manufacturing our drug candidates may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters such as fires, outbreak of epidemics or diseases, and the PRC and global economic conditions. A significant increase in the costs of supplies may directly and negatively affect our profit margins and, ultimately, our business, financial conditions, results of operation and prospects.

We may fail to maintain and predict inventory levels properly.

We are required to maintain optimal inventory levels in order to successfully meet our customers’ demand in the future. However, we may not be able to maintain proper inventory levels of our products, as a result of rapid changes in clinical demands, and uncertainty of product developments and launches. There can be no assurance that we can accurately predict these trends and events and avoid over-stocking or under-stocking our products. Further, demand for products could change significantly between the time when the products are ordered and the time they are ready for delivery.

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Inventory levels in excess of demand may result in inventory write-downs, expiration of our products or an increase in inventory holding costs and a potential negative effect on our liquidity. On the other hand, if we underestimate demand, we may experience inventory shortages which may, in turn, result in unfulfilled customer orders, leading to a negative impact on our customer relationships.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we and our current or future collaborating partners are unable to protect our intellectual property rights worldwide, or if the scope of such intellectual property rights obtained is not sufficiently broad or a compulsory license is issued, third parties could develop and commercialize drug candidates and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially and adversely affected.

We seek to protect the drug candidates and technologies that we consider commercially important by filing patent applications in China and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. For further information on our patent portfolio, see “Business — Intellectual Property.” If we or our current or future collaborating partners are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we and our collaboration partner may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we and our current or future collaborating partners may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. As of the Latest Practicable Date, we have not obtained patent protections for certain of our early-stage drug candidates. Although we plan to initiate patent applications in due course, currently there is no patent protection available for such drug candidates until the relevant patent applications are successful.

The requirements for patentability differ in certain jurisdictions. For example, methods of treatment of diseases are not patentable subject matters in China. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, according to the Patent Law of the People’s Republic of China (《中華人民共和國專利法》) (the “**PRC Patent Law**”), for public health purposes, the China National Intellectual Property Administration (CNIPA) may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these

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jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patent or patent application relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations and prospects may be adversely affected. To our best knowledge, as of the Latest Practicable Date, drug products belonging to the same class of our product candidates had not been subjects of compulsory licensing in China.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements or clauses with parties who have access to confidential or patentable aspects of our research and development output, such as our employees and third-party contractors, any of these parties may breach such agreements or clauses and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and the U.S., have adopted the “first-to-file” system, under which the first inventor to file a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

In addition, under the PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to file in advance to CNIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future are issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold, acquire or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Consequently, we do not know whether any of our platform advances and drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

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Our patent rights may be challenged and invalidated.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other jurisdictions. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings challenging our patent rights or the patent rights of others. If we are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which our intellectual properties are subject, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we are unsuccessful in any inventorship disputes to which we are subject, we may lose valuable intellectual property rights, such as exclusive ownership. If we are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

Specifically, despite measures we take to obtain patent protection with respect to our major drug candidates and technologies, any of such issued patents could be narrowed, challenged or invalidated due to any interference proceedings or other priority or validity disputes. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigations in the U.S., for example, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar patent invalidity claims before administrative bodies in China, the U.S. or in other jurisdictions, even outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, interference proceedings, derivation, invalidation, revocation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and

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unenforceability is unpredictable. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer adequately cover and protect our drug candidates. Even if a third party does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against such third party and others.

Even if we obtain patent protection for our drugs and drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize drugs and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially and adversely affected.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for invention in the PRC and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Generic or biosimilar medications may obtain marketing approval following our patent expiration. The patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates. For the expiration dates of our issued patents for our drug candidates, please see “Business — Intellectual Property.” Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our intellectual property or being sued for infringing, misappropriating or other violating the intellectual property rights of third parties, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other

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violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate more resources to enforce and defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Therefore, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

Moreover, we may not be able to detect infringement against our patents. Even if we detect infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, such as the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce our patents against such third party.

Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our collaboration partner, our or their patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates, leave our technology or drug candidates without patent protection, allow third parties to commercialize our technology or drug candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our drug candidates without infringing third party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

In addition, our commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Defending ourselves against third parties' intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team's attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

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In the event that third parties assert infringement claims against us, we cannot assure you that the outcome would be in our favor, as whether a product infringes on third parties’ intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge a third-party intellectual property right may be high. If we were found by courts or other competent authorities to have infringed on the patent or other intellectual property rights of third parties, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing our drugs and drug candidates, or at least delay the development or commercialization process. We may also be required to obtain and maintain licenses from third parties in order to continue the development of our drug candidates or our general operations, which may have an adverse impact on our financial position and profitability. Even if the litigations or other proceedings are resolved in our favor, our involvement in such proceedings may attract publicity, thereby having a substantial adverse effect on our reputation and brand name.

We may not be able to adequately enforce our intellectual property rights in foreign jurisdictions.

As we sell and intend to sell our successfully commercialized drugs in various jurisdictions including China, the U.S., Europe, Uzbekistan and elsewhere, we are dependent on the laws of a wide range of jurisdictions to protect, maintain and enforce our intellectual property rights throughout the world. We have not yet sought intellectual property protection in all jurisdictions where we ultimately intend to sell our products, and as a result of commercial pressures or otherwise, we may significantly expand our business into such jurisdictions without the benefit of clear, enforceable intellectual property protections. The laws of these jurisdictions may also be insufficient to protect our intellectual property rights to the same extent or in the same manner as the laws of the jurisdictions in which we currently have sought intellectual property protections or of the jurisdictions where investors may be located.

Many companies have encountered significant problems in protecting, obtaining and defending intellectual property rights in certain jurisdictions. In particular, the legal systems of certain developing countries do not favor or consistently enforce patents, trade secrets, trademarks and other forms of intellectual property protection, which could make it difficult and time-consuming to stop the infringement, misappropriation or other violation of our intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and sell or import products made using our inventions in and into our markets of interest. These products may compete with our products, and our existing patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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Failure to obtain the patent term adjustment or extension for NMPA-approved pharmaceutical products could increase the risk of early generic competition for our products in China.

In China, the PRC Patent Law provides a drug-patent linkage system. According to the drug-patent linkage system, "during the review and approval of marketing authorization of a drug, when the applicant of drug marketing authorization and the patentee or interested party have dispute regarding patent rights of the drug under application, relevant parties may file a lawsuit with the people's court and pursue judgement for whether the relevant technical solution of the drug under application falls within the scope of protection of the relevant patent rights. The Drug Regulatory Authority under the State Council may make a decision on whether to suspend the drug marketing authorization according to effective judgment of the people's court within specified period. The applicant of drug marketing authorization and the patentee or interested party may also apply for an administrative ruling to the patent administration department of the State Council regarding patent right dispute related to the drug under application of marketing authorization."

In addition, the PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, and stipulates that the patent administration department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China, to compensate for the time spent for the review and examination and approval of the listing of a new drug on the market. The compensated extension shall not exceed five years, and the total valid patent term after the new drug is approved for the market shall not exceed 14 years.

Also, according to the PRC Patent Law, a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for unreasonable delays by the CNIPA at the request of the patentee, in excess of a patent applicant's own delays during the prosecution process. However, if we fail to apply for them in accordance with the applicable NMPA requirements, we may not be able to benefit from those benefits.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We currently own issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the CNIPA and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are

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unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature in the future, upon regulatory approval, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks and we may encounter lawsuits related to trademarks and trade names. We may be unsuccessful to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements or clauses with parties that have access to trade secrets or confidential information, such as our employees, collaboration partners, outside scientific collaborators, contract manufacturers, and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements or clauses. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements or clauses may breach or violate the terms of any such agreements or clauses and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered

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into such agreements or clauses with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

In addition, while we typically require our employees and contractors who may be involved in the conception or development of intellectual property to enter into agreements or clauses assigning such intellectual property to us, we may be unsuccessful in executing such an agreement or clause with each party who in fact develops intellectual property that we regard as our own. Furthermore, even when we obtain agreements or clauses assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements or clauses may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements or clauses with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement or clause

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with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Intellectual property and other laws and regulations are subject to development, which could diminish the value of our intellectual property and impair the intellectual property protection of our drug candidates.

Our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in different jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

Under the America Invents Act, the AIA, enacted in 2011, the U.S. moved to first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literatures often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

There could be similar changes in the laws of China, such as the amendment to the PRC Patent Law which was promulgated in October 2020. See “— Failure to obtain the patent term adjustment or extension for NMPA-approved pharmaceutical products could increase the risk of early generic competition for our products in China.” Such changes in laws either of China or foreign jurisdictions may impact the value of our patent rights or our other intellectual property rights, all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial conditions, results of operations and prospects.

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Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to non-compliance with those requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, the United States Patent and Trademark Office (the “USPTO”) and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and other similar governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through in-licenses and acquisitions, and we may face disputes regarding to our historical patent transfers.

Because our programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

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Intellectual property rights do not necessarily protect us from all potential threats.

The degree of protection afforded by our intellectual property rights is essentially uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The limitations of currently available intellectual property protection regimes include that:

- others may be able to make products that are similar to any of our drug candidates or utilize similar or alternative technology that are not covered by the claims of the patents that we own or have exclusively licensed now or in the future;
- we or our current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;
- we or our current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- patents that may be issued from our pending patent applications may not provide us with any competitive advantages, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sales of the related product, the commercial value of our patents may be limited;
- the proprietary technologies on which we rely may not be patentable;
- the patents of others may materially and adversely affect our business; and
- we may choose not to file a patent for certain trade secrets or know-how, yet a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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RISKS RELATING TO GOVERNMENT REGULATIONS

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated.

All jurisdictions in which we intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. These jurisdictions all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development and approval, manufacturing, marketing, sales and distribution of pharmaceutical products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements in the jurisdictions we operate or target to operate in the future at any time during the drug development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include but are not limited to a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially and adversely affect our business, financial condition, results of operations and prospects.

Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant laws, regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and adversely affect our reputation and financial results.

The regulatory approval processes of the NMPA, the Center for Pharmaceutical Products Safety and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are unable to obtain without undue delay any regulatory approval for our drug candidates in our targeted markets, our business may be substantially harmed.

We are subject to risks associated with obtaining regulatory approvals. Difficulties and failures in doing so may expose us to various harms. The time required to obtain approvals from the relevant regulatory authorities in different jurisdictions is unpredictable but typically takes 10 to 15 years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

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We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our drug candidates will be approved for sale in those jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to different markets in compliance with different regulatory processes.

We may fail to receive the regulatory approvals from the NMPA, the Center for Pharmaceutical Products Safety or other comparable regulatory authorities for our drug candidates due to a number of reasons, including:

- disagreement in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- insufficient or suboptimal data collected from the clinical trials, or failure of our clinical trial results to meet the level of statistical and medical significance required for approvals;
- failure of our clinical trial process to pass GCP inspections;
- unexpected changes in regulations, testing requirements, or approval policies that render our preclinical and clinical data insufficient for approval;
- failure of our clinical sites to pass audits carried out by the NMPA, the Center for Pharmaceutical Products Safety or other comparable regulatory authorities, resulting in a potential invalidation of our research data; and
- findings of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies, such as failure to pass cGMP inspections.

Additionally, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in various jurisdictions could result in significant delays, difficulties and costs for us, and we cannot assure you that we will be able to meet regulatory requirements of different jurisdictions. The NMPA, the Center for Pharmaceutical Products Safety or other comparable regulatory authorities may require more information to support approval, including additional preclinical or clinical data, which may result in delay in regulatory approval and commercialization plans or denial of regulatory approval. In the case where an approval is issued, regulatory authorities may approve fewer indications, including undesired indications, of our drug candidates than the indications we applied for.

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Also, failure to obtain regulatory approvals in a timely manner, or at all, or failure to obtain regulatory approvals with an intended scope of indications could have a negative impact on the commercial prospects of our drug candidates, and may cause reputational damage. If any of our drug candidates fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities or does not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such drug candidate despite the significant amount of resources we would have spent on its development, which could materially adversely affect our business, financial condition, results of operations and prospects.

We are subject to registration, review and other requirements of the PRC and the overseas regulatory authorities for cross-border sales or licensing of technology as well as operations related to genetics and data safety.

China oversees and regulates the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (《技術進出口管理條例》) promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (《技術進出口合同登記管理辦法》), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology. We may in the future transfer or out-license our patents or technology to overseas partners, or acquire or in-license patents or technology from overseas partners, or enter into agreements with overseas CROs for their technical support to assist us with the development of individual drug candidates, which may be deemed to constitute the import or export of technology under the regulations. As a result, such transfers may be required to be registered with applicable governmental authorities. We are also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we are required to obtain approval from or complete relevant filing with the Office of Human Genetic Resources Management under the Ministry of Science and Technology who will conduct genetics and data safety review. There is no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret or individual privacy may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our

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research and development of drug candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

We or the parties on whom we rely may fail to maintain or renew necessary licenses, permits, certificates or regulatory approvals for the development, manufacture and sales and distribution of our drugs and future approved drug candidates.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, manufacture, sell and distribute our drugs and future approved drug candidates. Please see “Business — Licenses, Permits and Approvals.” Third parties, such as suppliers, distributors, CROs, and CMOs on whom we may rely to develop, manufacture, sell and distribute our products, may be subject to similar requirements. We and our business partners may also be subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may develop from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or our business partners fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired.

Any developments in the standards used by governmental authorities in considering whether to renew or reassess our or our business partners’ licenses, permits and certifications, as well as enactment of any new regulations that may restrict the operation of our business, may also decrease our revenue and increase our costs, which in turn could materially and adversely affect our profitability and prospects. Furthermore, if the interpretation or implementation of existing laws and regulations develop, or new regulations come into effect, requiring us or the parties on whom we rely to obtain any additional permits, licenses or certifications that were previously not required to operate our business, there can be no assurance that we or the parties on whom we rely will successfully obtain such permits, licenses or certifications.

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Developments in laws and regulations relating to the pharmaceutical industry may result in additional compliance risks and costs.

In China, Uzbekistan and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes relating to the pharmaceutical industry and the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. See also “— Risks Relating to Sales and Distribution and Commercialization of Our Drugs and Drug Candidates — Our drug candidates may not be covered by insurance or reimbursement programs or may become subject to unfavorable insurance policies or reimbursement practices, either of which could harm our business, and we may be subject to unfavorable pricing regulations, which could make it difficult for us to sell our drugs profitably.”

As certain of our drug candidates were in commercial or near-commercial stages as of the Latest Practicable Date, these legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our drug and future approved drug candidates. Moreover, because these laws and regulations are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these laws and regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We routinely receive, collect, generate, store, process, transmit and maintain medical data, treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives, regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

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Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients’ privacy, they may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence.

In addition, our clinical trials also frequently involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with the applicable laws and regulations or our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs, CMOs and other third-party contractors for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure.

Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Noncompliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could have a material adverse effect on our business, financial condition and results of operations.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties and other negative consequences if we fail to comply with these regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA, the Center for Pharmaceutical Products Safety or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, storage, distribution, adverse event reporting, advertising, promotion, sampling, recordkeeping and post-marketing studies for the drug will be subject to extensive and ongoing or additional regulatory requirements on pharmacovigilance. These requirements include

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submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any CMC, variations, continued compliance with cGMPs, GCPs, good storage practices and good vigilance practices and potential post-approval studies for the purposes of license renewal.

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including, if applicable, phase 4 trials for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved by the NMPA, the Center for Pharmaceutical Products Safety or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug candidates, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the NMPA, the Center for Pharmaceutical Products Safety or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

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We may be directly or indirectly subject to applicable anti-kickback, anti-bribery, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain the NMPA’s approval for any of our drug candidates and begin commercializing our drugs in China in the future, our operations may become subject to various PRC fraud and abuse laws, including the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and PRC Criminal Law (《中華人民共和國刑法》). These laws may impact, among others, our proposed sales, marketing and education programs.

Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

In addition, we are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. The PRC government has taken increasingly stringent measures to correct corruptive practices in the pharmaceutical industry since 2023. For example, in May 2024, multiple governmental departments including the National Health Commission jointly issued the Key Points for the Correction of Malpractice in the Purchase and Sales of Medical Products and Medical Services in 2024 (2024年糾正醫藥購銷領域和醫療服務中不正之風工作要點), emphasizing the need to rectify corruption in the pharmaceutical industry. Moreover, although currently our business operations are primarily in China, we are subject to the Foreign Corrupt Practices Act (the “FCPA”). The FCPA generally prohibits us from making improper payment to non-U.S. officials for the purpose of obtaining or retaining business. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. See also “— Risks Relating to Our Operations — Our Directors, employees, principal investigators, commercial partners and independent contractors may engage in misconduct or other improper activities, including

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non-compliance with regulatory standards and requirements, which could harm our reputation and subject us to penalties and significant expenses that have a material and adverse effect on our business, financial condition and results of operations.”

We are subject to environmental protection, health and safety laws and regulations, and failure to comply with them could result in fines, penalties, or costs that may materially adversely affect the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our new manufacturing facility construction project can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the facility. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our drug candidates as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, and health and safety laws and regulations, we may be subject to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions in our business operations. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial condition, results of operations and prospects.

In addition, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facility during the process of discovery, testing, development and manufacturing of our drug candidates. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. Other adverse effects could result from such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facility temporarily, or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects.

We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Holders of H Shares, being non-PRC resident individuals or non-PRC resident enterprises, whose names appear on the register of members of H Shares of our Company, are subject to PRC income tax in accordance with the applicable tax laws and regulations, on dividends received from us and gains realized through the sale or transfer by other means of shares by such shareholders.

According to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) and the Implementation Regulations for the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), both came into effect on January 1, 2019, the tax applicable to non-PRC resident individuals is proportionate at a rate of 20% for any dividends obtained from within China or gains on transfer of shares and shall be withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the “Arrangements”) (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) executed on August 21, 2006, the PRC Government may levy taxes on the dividends paid by PRC companies to Hong Kong residents in accordance with the PRC laws, but the levied tax (in the case the beneficial owner of the dividends are not companies directly holding at least 25% of the equity interest in the company paying the dividends) shall not exceed 10% of the total dividends.

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), which was newly revised and implemented on December 29, 2018, and the Implementation Regulations for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》), which was newly revised and implemented on December 6, 2024, if a non-resident enterprise has no presence or establishment within China, or if it has established a presence or establishment but the income obtained has no actual connection with such presence or establishment, it shall pay an enterprise income tax on its income derived from within China with a reduced rate of 10%. Pursuant to the Arrangements, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or in accordance with the PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of the total amount of dividends if the Hong Kong resident is a company that directly owns at least 25% of the capital of the PRC resident enterprise paying dividends; (ii) otherwise, 10% of the total amount of dividends.

The interpretation and enforcement of applicable tax laws and regulations in the PRC by the PRC tax authorities, including whether and how income tax will be levied on non-PRC resident shareholders, will be determined according to the laws and regulations then in effect. Non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

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Laws and regulations over currency conversion may affect our ability to pay dividends or fulfill other obligations.

Our revenue and expenses are substantially denominated in Renminbi, and the net [REDACTED] from the [REDACTED] and dividends we pay on our H Shares, if any, will be in Hong Kong dollars. Under China’s existing foreign exchange regulations, following the completion of the [REDACTED], we will be able to make current account foreign exchange transactions, including paying dividends in foreign currencies without prior approval from SAFE, by complying with certain procedural requirements.

However, the foreign exchange policies regarding payment of dividends in foreign currencies may change from time to time in the future. In addition, any insufficiency of foreign exchange may restrict our ability to obtain sufficient foreign exchange for dividend payments to shareholders, our ability to obtain foreign exchange through offshore financing and other foreign exchange related matters may also be affected.

There exist uncertainties in effecting service of legal process, enforcing foreign judgments or bringing original actions in China against us or our management based on Hong Kong or other foreign laws.

We are incorporated under the laws of the PRC with limited liability, and substantially all of our assets are located in China. A majority of our Directors, Supervisors and senior management personnel also reside in China, and substantially all of their assets are located in China. As a result, it may not be possible for [REDACTED] to effect service of process upon us or our Directors, Supervisors and senior management personnel in China.

On July 14, 2006, the Supreme People’s Court of PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “2006 Arrangement”). Under the 2006 Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the 2006 Arrangement in which a Hong Kong court or a PRC court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the 2006 Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the 2006 Arrangement remain uncertain.

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On January 18, 2019, the Supreme People’s Court of PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”), which seeks to establish a mechanism with further clarification on and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong Special Administrative Region and PRC. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement has come into effect on January 29, 2024 and superseded the 2006 Arrangement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However, we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

Furthermore, China has not entered into treaties or arrangements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the U.S., the United Kingdom, or most other western countries, and Hong Kong has no arrangement for the reciprocal enforcement of judgments with the U.S. As a result, recognition and enforcement in PRC or Hong Kong of judgment of a court in the U.S. or any other jurisdictions mentioned above in relation to any matter that is not subject to a binding arbitration provision may be difficult or impossible.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We may continue to incur significant research and development expenses and other expenses related to our ongoing operations and not be able to generate sufficient revenue to achieve and maintain profitability in the future.

Investment in the development of pharmaceutical products is highly speculative as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we primarily funded our operations through a combination of equity and debt financing supplemented by cash generated from operations. We expect to continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, though we recorded a net profit of RMB6.4 million and RMB42.4 million in 2023 and the nine months ended September 30, 2023, respectively, such net profit position turned into a net loss position in the nine months ended September 30, 2024, amounting to RMB156.4 million.

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Substantially all of our significant operating expenses during the Track Record Period resulted from our research and development expenses and administrative expenses. See “Financial Information — Description of Major Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income.” Our ability to generate sufficient revenue to achieve and maintain profitability depends significantly on our success in advancing drug candidates into later stages of clinical development, obtaining regulatory approvals for each drug candidate, and commencing commercialization of these future approved drug candidates, which we may not be able to do in a timely manner or at all.

We expect to continue to incur significant research and development expenses and other expenses related to our ongoing operations in the foreseeable future and that our net loss may increase if and as we, among others:

- continue to advance the clinical trials and preclinical studies of our product pipeline;
- seek to discover or develop additional drug candidates and initiate preclinical, clinical or other studies for these new drug candidates to further expand our product pipeline;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- manufacture our drug candidates for clinical trials and for commercial sale;
- commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- acquire or in-license other drug candidates, intellectual property assets and technologies;
- develop, maintain, expand and protect our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations, insurance and other expenses associated with operating as a [REDACTED] following the completion of the [REDACTED].

Even if we manage to achieve profitability in the future, we may not be able to sustain or increase profitability on an ongoing basis. Our net loss position has had, and will continue to have, an adverse effect on our working capital and shareholders’ equity. Our failure to become and remain profitable may also impact investors’ perception of the potential value of

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our Company and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the [REDACTED] of our H Shares. A decline in the [REDACTED] of our H Shares could cause potential [REDACTED] to lose all or part of their [REDACTED] in our business.

If we determine our intangible assets to be impaired, our results of operations and financial condition may be adversely affected.

Our intangible assets consist of in-licenses for our drug candidates, capitalized development costs in relation to three generic drugs, namely dapoxetine, rebamipide and brexpiprazole, software and intellectual properties. The value of our intangible assets is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may have to write off a significant portion of our intangible assets and record a significant impairment loss. In addition, our determination on whether intangible assets are impaired requires an estimation of the carrying amount and recoverable amount of an intangible asset. If the carrying amount exceeds its recoverable amount, our intangible assets may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. For details of our accounting policies with respect to intangible assets, see “Financial Information — Material Accounting Policies, Critical Accounting Judgments and Key Sources of Estimation Uncertainty.”

We had net current liabilities and net cash outflow during the Track Record Period, which may continue into the foreseeable future and expose us to liquidity risk.

We had net current liabilities of RMB119.6 million and RMB213.1 million as of December 31, 2023 and September 30, 2024, respectively. See “Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position.” Net current liabilities positions can expose us to liquidity and financial risks. In addition, we recorded net cash outflow in operating activities of RMB104.5 million in the nine months ended September 30, 2024. See “Financial Information — Liquidity and Capital Resources — Cash Flows.” These in turn could require us to seek financing from external sources such as debt issuance and bank borrowings, which may not be available on terms favorably or commercially reasonable to us, or at all. See also “— We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.” If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we primarily funded our operations through a combination of equity and debt financing, supplemented by cash generated from operations. Going forward, we expect our liquidity requirements will be satisfied by a combination of revenue generated from the sales of our commercialized products and out-licensing arrangements, existing cash and cash equivalents, bank loans, and net [REDACTED] from the [REDACTED]. Changes in our ability to fund our operations may affect our cash flow and results of operations. We may require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development or expansion of manufacturing capabilities. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- the amount and timing of any milestone and royalty payments we receive from or pay to our current or future collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- the cash requirements of any future acquisitions; and
- our headcount growth and the associated costs.

As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all.

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Our ability to raise funds will also depend on the prevailing financial, economic and market conditions and factors from other aspects, such as our relationship with commercial banks, many of which are beyond our control. See also “— Risks Relating to Our Operations — We are subject to the risks of doing business globally. Disruptions in the financial markets and economic conditions could affect our ability to raise capital.” If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities, or the commercialization of one or more of our drug candidates, which may adversely affect our business prospects.

We are entitled to certain preferential tax treatments and government grants, and the expiration of or changes to which or our failure to satisfy any condition for which would have an adverse effect on our results of operations.

During the Track Record Period, we enjoyed certain preferential tax treatments. The Company was accredited as a “High and New Technology Enterprise” in 2022 and may be entitled to a preferential tax rate of 15% for a term of three years starting from the year of accreditation. We cannot assure you that these preferential tax treatments will continue to be available to us in the future or that these preferential tax treatments will not be changed as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected.

In addition, we recognized government grants of RMB4.0 million, RMB1.1 million and RMB6.7 million in 2023 and the nine months ended September 30, 2023 and 2024, respectively. The timing, amount and criteria of government financial incentives are determined at the sole discretion of the PRC government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We do not have the ability to influence government authorities in making these decisions. Local government authorities may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project by project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, otherwise we may be deprived of all or part of the incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives may have an adverse effect on our results of operations. In addition, we may not be able to receive government grants in the future, which may have an adverse effect on our financial condition and results of operations.

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Any future increase in finance costs on borrowings for funding may affect our expansion in business and growth prospects.

During the Track Record Period, we obtained bank loans from reputable commercial banks in the PRC to fund our capital expenditures and working capital. We had borrowings of RMB279.5 million and RMB367.4 million as of December 31, 2023 and September 30, 2024, respectively. In addition, we recorded interest paid of RMB11.8 million, RMB7.5 million and RMB10.8 million in 2023 and the nine months ended September 30, 2023 and 2024, respectively. In the future, we may continue to fund our business operation, in part, on access to external financing, including borrowings. Any future increase in finance costs, whether due to rising interest rates, changes in credit market conditions, or unfavorable terms on new or refinanced debt, could significantly increase our cost of capital. Such higher borrowing costs could reduce the funds available for critical investments in research and development, commercialization of future approved drug candidates, manufacturing, and our business expansion efforts.

Additionally, increased finance costs could strain our cash flow and liquidity, particularly if our revenue growth cannot keep pace with the rising cost of debt. This could lead to difficulties in meeting debt obligations, which may, in turn, limit our ability to secure additional financing on favorable terms or at all. Any such constraints could delay or curtail planned growth initiatives, especially our extensive research and development activities and marketing and distribution efforts, limit our ability to compete effectively in the market, and materially and adversely affect our financial condition, results of operations, and business prospects. If we are unable to manage the risks associated with increased borrowing costs, our ability to execute our strategic objectives and sustain business growth could be adversely affected.

We may be subject to credit risk in collecting trade receivables due from our customers.

As of December 31, 2023 and September 30, 2024, our trade receivables amounted to RMB36.6 million and RMB12.6 million, respectively, which primarily represented the balances due from our customers in relation to the out-licensing of VV116, our provision of CRO services and the sales of our pharmaceutical products. As of December 31, 2023 and September 30, 2024, our allowance for credit losses on trade receivables amounted to RMB2.2 million and RMB1.7 million, respectively. Our liquidity and cash flow are directly affected by their ability to pay us in a timely manner, but we cannot assure you that they will not default on us in the future, despite our efforts to conduct credit assessments. If any of our customers' business, cash flow, conditions or results of operations deteriorates, it may be unable or unwilling to pay trade receivables owed to us promptly or at all. Bankruptcy or deterioration of the credit condition of our major customers could also materially and adversely affect our collection of trade receivables from them. If significant amounts due to us are not settled on time, we may need to incur additional significant write-down and our liquidity and cash flow may be adversely affected.

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RISKS RELATING TO OUR OPERATIONS

We have a limited operating history, which makes it difficult to evaluate our business and prospects, and our historical growth may not be indicative of our future performance.

We have a limited operating history and our operations to date have focused on conducting research and development activities and commercializing our drugs and drug candidates. As a result of our limited operating history, and particularly in light of the highly competitive nature of the pharmaceutical industry, it may be difficult to evaluate our current business and reliably predict our future performance. Our historical results may not provide a meaningful basis for evaluating our business, results of operations, financial condition and prospects, and we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors, and may not be able to achieve promising results in future periods. If we cannot address these risks and overcome these difficulties successfully, our business and prospects will suffer.

The loss of any key members of our senior management team or our inability to attract and retain highly skilled and qualified employees could adversely affect our business.

We are highly dependent the expertise and insights of our senior management. In addition, recruiting and retaining qualified scientific, clinical, manufacturing and sales personnel in the future will also be critical to our success. The loss of services of any of these individuals could delay or prevent the successful development of our drug candidates and achievement of our commercialization objectives.

Although we have not historically experienced unique difficulties in attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the pharmaceutical industry is intense and the pool of qualified candidates is limited. The departure of one or more of our senior management or key personnel, may subject us to risks relating to replacing them in a timely manner or at all, which may disrupt our operations and have a material and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we build and expand our commercialization team. We may not be able to attract and retain qualified employees on acceptable terms.

As we have significantly increased the size and capabilities of our organization since our inception, we may experience difficulties in managing our growth.

As our development and commercialization plans and strategies evolve, we must add additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

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- managing our relationships with third parties, including suppliers and partners;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies.

If we are not able to effectively manage our growth and further expand our organization, we may not be able to successfully develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially adversely affect our business, financial condition, results of operations and prospects.

Our Directors, employees, principal investigators, commercial partners and independent contractors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could harm our reputation and subject us to penalties and significant expenses that have a material and adverse effect on our business, financial condition and results of operations.

We are subject to the anti-bribery laws of various jurisdictions, particularly in China and the U.S. As our business expands, the applicability of the anti-bribery laws to our operations will increase. We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, commercial partners and independent contractors that could subject us to financial losses and sanctions imposed by government authorities, which may adversely affect our reputation. Our procedures and controls to monitor compliance with anti-bribery law may fail to protect us from reckless or criminal acts committed by our employees or other commercial partners. We could be liable for actions taken by them that violate anti-bribery, anti-corruption and other related laws and regulations in China, the U.S. or other jurisdictions. The government authorities may limit the sales of the products involved in any illegal or improper conduct engaged in by our employees or commercial partners. We may be subject to claims, fines or suspension of our operations. Our reputation, our sales activities or the price of our H Shares could be adversely affected if we are associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our employees or commercial partners.

During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations.

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However, we cannot assure you that there will not be any such instances in future. Any such misconduct committed against our interests, including past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

We are subject to the risks of doing business globally. Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

We are mainly operating in China and expanding our selling scale in Uzbekistan at present, and we may in the future expand our operations to other countries and regions on a global scale, and therefore our business could be subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- the burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

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In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships, which could cause our results to fluctuate and our revenue to decline. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially adversely affect our business and results of operations.

Developments in the economic, political or social conditions in our major operation location may materially and adversely affect our business, financial condition, results of operations and prospects.

We generate a substantial portion of our revenue from our operations in China. Accordingly, our business, results of operations, financial condition and prospects are subject to and influenced by the economic, political and social conditions in China. The PRC economy has experienced significant growth over the past decades since the implementation of China’s reform and opening-up policy. In recent years, the PRC government has implemented measures emphasizing the utilization of market forces in economic reform and the establishment of sound corporate governance practices in business enterprises. These economic reform measures may be adaptively adjusted from industry to industry or across different regions of the country. The overall economic growth is influenced by the governmental regulations and policies in relation to capital investments, monetary policies, regulations of financial services and institutions, preferential treatment to particular industries or companies and others. If the business environment in China changes, our business and its growth prospects may be adversely affected.

We cannot predict future changes in China’s economic, political and social conditions and the effect that new government policies would have on our business and prospects. Any actions and policies adopted by the PRC government could adversely affect our business, results of operations, financial condition and competitive position.

We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. In addition to the intellectual properties related litigations we may face as mentioned in “— We may become involved in lawsuits to protect or enforce our intellectual property or being sued for infringing, misappropriating or other violating the intellectual property rights of third parties, which could be expensive, time-consuming and unsuccessful,” we may also be involved in disputes or litigations relating to other issues, among others, breach of contract, environmental matters, and employment. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to actions taken by our counterparties, such as our suppliers, CROs, CMOs and

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other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

The occurrence of any future currency exchange rate fluctuations could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The value of the Renminbi against the U.S. dollar and other foreign currencies fluctuates from time to time and is affected by a number of factors, such as changes in the global economic conditions and the fiscal and foreign exchange policies. With the development of foreign exchange market and progress towards interest rate liberalisation and Renminbi internationalisation, the PRC government may in the future announce further reforms to the exchange rate system. We cannot assure you that the exchange rates of Renminbi against the Hong Kong dollar or the U.S. dollar will not change in the future.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any change in the exchange rate of the Renminbi to the U.S. dollar, the Hong Kong dollar or any other foreign currencies may affect the value of our [REDACTED] from the [REDACTED], and the value of, and any dividends payable on, our H Shares in foreign currencies. Further, there is no assurance that we will, at a certain exchange rate, have sufficient foreign currencies to meet our demand (if any) for foreign currencies in the future. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

We may engage in acquisitions or strategic partnerships in the future, which may increase our capital requirements, cause dilution for our Shareholders, cause us to incur debt or assume contingent liabilities or subject us to other risks.

From time to time, to enhance our growth, we may evaluate various acquisition and strategic partnership opportunities that we believe would benefit us in terms of product development, technology advancement or distribution network. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- substantial time and expenses incurred during negotiation, which do not guarantee the successful consummation of an acquisition or strategic partnership;
- impact on our financial results, such as occurrence of goodwill impairment charges and amortization expenses for intangible assets;
- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;

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- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, or failure to otherwise achieve intended synergies in the combined operations;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in the acquired business we discover after such acquisition, which may subject us to penalties, lawsuits or other liabilities.

We may not be able to identify attractive targets, and we have limited experience in acquisitions. In addition, we may not be able to successfully acquire the targets identified despite spending a significant amount of time and resources on pursuing such acquisition. Furthermore, integration of an acquired company, its intellectual property or technology into our own operations is a complex, time-consuming and expensive process. The successful integration of an acquisition may require, among other things, that we integrate and retain key management, sales and other personnel, integrate the acquired technologies or services from both an engineering and a sales and marketing perspective, integrate and support preexisting supplier, distribution and customer relationships, coordinate research and development efforts, and consolidate duplicate facilities and functions. The geographic distance between companies, the complexity of the technologies and operations being integrated, and the disparate corporate cultures being combined may increase the difficulties of integrating an acquired company or technology. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

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Increased labor costs may slow our growth and affect our operations.

Our operations require the use of technical skills and know-how of our employees, and our success depends in part on our ability to attract, retain and motivate a sufficient number of qualified employees. We have implemented a number of initiatives in an effort to attract, retain and motivate our qualified and competent staff. There is no assurance that these measures will be effective or that supply of skilled labor in local markets will be sufficient to fulfil our needs. Competition for competent and skilled labor is intensive in the industry. Our failure to hire and retain enough skilled employees could delay the anticipated preclinical studies or clinical trials timeframe or receipt of regulatory approvals to commercialize our drug candidates, or result in our expenses exceeding our initial budget. Any of the foregoing changes could have a material adverse effect on our business, profitability and prospects.

Further, substantially our entire workforce is employed in China. The average labor cost in China has been steadily increasing over the past years as a result of government-mandated wage increases and other changes in the PRC labor laws. Further changes in the labor laws, rules and regulations may be promulgated by the Chinese government in the future and our operations may be materially adversely affected if such laws, rules or regulations impose additional burden on the employers. The labor cost will continue to increase in the future which is in line with the economic growth in China. Competition for employees would require us to pay higher wages, which would result in higher labor costs.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. We maintained certain types of insurance, such as clinical trial liability insurance, work safety liability insurance and employer’s liability insurance. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facility or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

Our property valuation is based on certain assumptions which, by their nature, are subjective and uncertain and may materially differ from actual results.

The Property Valuation Report prepared by AVISTA Valuation Advisory Limited, an independent property valuer, set out as Appendix III to this document with respect to the appraised values of our properties is based on various assumptions, which are subjective and uncertain in nature. The assumptions that AVISTA Valuation Advisory Limited used in the property valuation report include that the estimated price will not be inflated or deflated by special terms or circumstances such as atypical financing, sale and leaseback arrangement, special considerations or concessions granted by anyone associated with the sale, or any element of special value or costs of sale and purchase or offset for any associated taxes. And

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no allowance has been made in the Property Valuation Report for any charges, mortgages or amounts owing on any of the Properties valued nor for any expenses or taxation which may be incurred in effecting a sale. Certain of the assumptions used by AVISTA Valuation Advisory Limited in reaching the appraised value of our properties may be inaccurate or unreasonable. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the appraised value of our properties may differ materially from the price we could receive in an actual sale of the properties in the market and should not be taken as their actual realizable value or an estimation of their realizable value. You should not place undue reliance on such values attributable to these properties as appraised by AVISTA Valuation Advisory Limited.

Our risk management and internal control systems may not fully protect us against various risks inherent in our business.

We have established risk management and internal control systems consisting of the relevant risk management policies and risk control procedures to manage our risk exposures, primarily our operational risks, legal risks and financial risks. However, we may not be successful in implementing our risk management and internal control systems. While we seek to continue to enhance such systems from time to time with future expansion of our business, we cannot assure you that our risk management and internal control systems are adequate or effective notwithstanding our efforts, and any failure to address any potential risks and internal control deficiencies could materially and adversely affect our business, financial condition and results of operations.

Since our risk management and internal control systems depend on the implementation by our employees, we cannot assure you that all of our employees will adhere to such policies and procedures, and the implementation of such policies and procedures may involve human errors or mistakes. Moreover, our growth and expansion may affect our ability to implement stringent risk management and internal control policies and procedures as our business evolves. If we fail to timely adopt, implement and modify, as applicable, our risk management and internal control policies and procedures, our business, financial condition and results of operations could be materially and adversely affected.

Our internal information technology systems, or those used by our CROs, CMOs or other contractors, may fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our current or future CROs, CMOs and other service providers are vulnerable to damage from cyber-attacks, computer viruses, malicious codes, unauthorized access, employee theft or misuse, natural disasters, fire, power loss, terrorism, war, and telecommunication and electrical failures, among other things. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or

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reproduce the data. To the extent that any disruption or security breach may result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed. In addition, a security breach may result in the loss of, damage to, or public disclosure of personally identifiable information, and such an event could have serious negative consequences, including disputes, regulatory action, investigation, litigation, fines, penalties and damages, and time-consuming and expensive litigation, any of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our reputation is important to our business success, and damage to our reputation may adversely affect our business.

We, our Shareholders, Directors, officers, employees, collaboration partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees, collaboration partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation and commercialization. As a result, we may be required to spend significant time and incur substantial costs to respond and protect our reputation, and we cannot assure you that we will be able to do so within a reasonable period of time, or at all, in which case our business, results of operations, financial condition and prospects may be materially and adversely affected.

We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control.

Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

Our business could be adversely affected by the effects of epidemics, including COVID-19, avian influenza, severe acute respiratory syndrome (SARS), influenza A (H1N1), Ebola or another epidemic. Any such occurrences could cause severe disruption to our daily operations and may even require a temporary closure of our offices and laboratories.

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Changes in and international trade policies may affect our business operations.

Governments around the world may make significant changes in their trade policies and/or take certain actions that may materially impact international trade, such as imposing several rounds of tariffs. Any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future drug products, the competitive position of our future drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or may prevent us from selling our future drug products in certain countries. If any new tariffs, legislation and regulations are implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition and results of operations.

The evolving trade disputes may escalate going forward and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships among the relevant countries or regions. Trade disputes, tensions and political concerns among the relevant countries or regions may therefore adversely affect our business, financial condition, results of operations, cash flows and prospects.

RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] for our H Shares and there can be no assurance that an active market would develop, and the price and [REDACTED] volume of our H Shares may be volatile.

No [REDACTED] currently exists for our H Shares. The initial [REDACTED] for our H Shares to the public will be the result of negotiations between our Company and the [REDACTED] (on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the H Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in, the H Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid trading market for our H Shares will develop, especially during the period when a certain portion of our H Shares may be subject to lock-up, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] or [REDACTED] of the H Shares will not decline following the [REDACTED].

In addition, the [REDACTED] and [REDACTED] of the H Shares may be subject to significant volatility in responses to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the [REDACTED] of the H Shares of other companies engaging in similar business may affect the price and [REDACTED] of our H Shares. In addition to

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market and industry factors, the [REDACTED] and [REDACTED] of our H Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting the pharmaceutical markets, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] on the [REDACTED] have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance.

You will incur immediate and substantial dilution and may experience further dilution in the future.

The [REDACTED] of our H Shares is higher than the net tangible asset value per H Share immediately prior to the [REDACTED]. Therefore, purchasers of the our H Shares in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value.

In order to expand our business, we may consider [REDACTED] and [REDACTED] additional Shares in the future. Purchasers of the our H Shares may experience dilution in the net tangible asset value per share of their H Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per H Share at that time. Furthermore, we may issue Shares pursuant to the Share Schemes, which would further dilute Shareholders’ interests in our Company.

Future sales or perceived sales of our H Shares in the [REDACTED] by major Shareholders following the [REDACTED] could materially and adversely affect the price of our H Shares.

Future sales or perceived sales by our existing Shareholders of our H Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our H Shares. Only a limited number of the H Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our H Shares in the [REDACTED] or the perception that these sales may occur could significantly decrease the prevailing [REDACTED] of our H Shares and our ability to raise equity capital in the future.

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Our Controlling Shareholders have substantial control over our Company and their interests may not be aligned with the interests of the other Shareholders.

Upon completion of the [REDACTED], our Controlling Shareholders will hold [REDACTED]% of our total issued and outstanding Shares (assuming the [REDACTED] is not exercised). As a result, our Controlling Shareholders, will have significant influence over our business, including decisions regarding mergers, consolidations, liquidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions.

It may take actions that are not in the best interest of us or our other Shareholders. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could have the effect of depriving our other Shareholders of the opportunity to receive a premium for their shares as part of a sale of our Company and may reduce the price of the H Shares. This concentrated control will limit your ability to influence corporate matters and could discourage others from pursuing any potential merger, takeover or other change of control transactions that other holders of our shares may view as beneficial.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our H Shares for a return on your [REDACTED].

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the research and development, regulatory filings and commercialization of our drug candidates. As a result, we might not pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] in our H Shares as a source for any future dividend income. For more details on our dividend policy, see “Financial Information — Dividends.”

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

Without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A. Were any of our competitors that are not [REDACTED] on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

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We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the net [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our Shareholders. We plan to use the net [REDACTED] from the [REDACTED] to, among other things, conduct clinical trials in China and other jurisdictions on our drug candidates and to expand our sales and marketing staff in preparation for the approval and commercialization of our drug candidates. For details, see “Future Plans and Use of [REDACTED].” However, our management will have discretion as to the actual [REDACTED] of our net [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

Facts, forecasts and statistics in this document relating to pharmaceutical markets may not be fully reliable.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources, including information provided or published by government agencies, and we can guarantee neither the quality nor reliability of such source materials. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, the information from official government sources has not been independently verified by us, the Sole Sponsor, the [REDACTED], the [REDACTED], any of their respective directors, employees, agents or advisers or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate or not comparable to statistics produced for other economies. Accordingly, the information from official government sources contained herein should not be unduly relied upon. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

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You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We do not have sufficient control over the press and media coverage, and analysts might issue negative views or recommendations on us, which could have an adverse effect on the [REDACTED] of H Shares. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information.

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in making your [REDACTED] decision regarding our H Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our H Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] in the [REDACTED]. By applying to purchase our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

In preparation for the [REDACTED], our Company has sought and [has been granted] the following waivers from strict compliance with the relevant provisions of the Listing Rules and the following exemption from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

WAIVER IN RESPECT OF MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rules 8.12 and 19A.15 of the Listing Rules, we must have a sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong.

Our headquarters and most of our business operations are based, managed and conducted in the PRC. As our executive Directors play very important roles in our business operation, it is in our best interest for them to be based in the places where our Company has significant operations. We consider it practicably difficult and commercially unreasonable for us to arrange for two executive Directors to be ordinarily reside in Hong Kong, either by means of relocation of our executive Directors to Hong Kong or appointment additional executive Directors. Therefore, we do not have, and in the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rules 8.12 and 19A.15 of the Listing Rules.

Accordingly, we have applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rules 8.12 and 19A.15 of the Listing Rules, provided that our Company implements the following arrangements:

- (a) we have appointed Dr. Tian and Ms. Au Wing Sze (區詠詩) (“**Ms. Au**”) as our authorized representatives pursuant to Rule 3.05 of the Listing Rules. The authorized representatives will act as our Company’s principal channel of communication with the Hong Kong Stock Exchange. The authorized representatives will be readily contactable by phone, facsimile (if any) and email to promptly deal with enquiries from the Hong Kong Stock Exchange, and will also be available to meet with the Hong Kong Stock Exchange to discuss any matter within a reasonable period of time upon request of the Hong Kong Stock Exchange;
- (b) when the Hong Kong Stock Exchange wishes to contact our Directors on any matter, each of the authorized representatives will have all necessary means to contact all of our Directors (including our independent non-executive Directors) promptly at all times. Our Company will also inform the Hong Kong Stock Exchange as soon as practicable in respect of any changes in the authorized representatives in accordance with the Listing Rules. We have provided the Hong Kong Stock Exchange with the contact details (i.e. mobile phone number, office phone number (if any), email address and fax number (if any)) of all Directors to facilitate communication with the Hong Kong Stock Exchange;

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- (c) we confirm and will ensure that all Directors who do not ordinarily reside in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and can meet with the Hong Kong Stock Exchange within a reasonable period upon the request of the Hong Kong Stock Exchange;
- (d) we have appointed Somerley Capital Limited as our compliance advisor upon [REDACTED] pursuant to Rule 3A.19 of the Listing Rules for a period commencing on the [REDACTED] and ending on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED]. Our compliance advisor will have access at all times to our authorized representatives, our Directors and our senior management as prescribed by Rule 3A.23 of the Listing Rules and will act as the additional channel of communication with the Hong Kong Stock Exchange when the authorized representatives are not available; and
- (e) meetings between the Hong Kong Stock Exchange and our Directors can be arranged through our authorized representatives or our compliance advisor, or directly with our Directors within a reasonable time frame.

WAIVER IN RESPECT OF APPOINTMENT OF JOINT COMPANY SECRETARY

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, we must appoint a company secretary who, by virtue of his/her academic or professional qualifications or relevant experience, is, in the opinion of the Hong Kong Stock Exchange, capable of discharging the functions of the company secretary. Note 1 to Rule 3.28 of the Listing Rules provides that the Hong Kong Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (a) a member of The Hong Kong Chartered Governance Institute;
- (b) a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and
- (c) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

Note 2 to Rule 3.28 of the Listing Rules further provides that the Hong Kong Stock Exchange considers the following factors in assessing the “relevant experience” of the individual:

- (a) length of employment with the issuer and other issuers and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;

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- (c) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

Pursuant to Chapter 3.10 of the Guide, the Stock Exchange will consider a waiver application by an issuer in relation to Rules 3.28 and 8.17 of the Listing Rules based on the specific facts and circumstances. Factors that will be considered by the Stock Exchange include:

- (a) whether the issuer has principal business activities primarily outside Hong Kong;
- (b) whether the issuer was able to demonstrate the need to appoint a person who does not have the Acceptable Qualification (as defined under Note 1 to Rule 3.28 of the Listing Rules) nor Relevant Experience (as defined under Note 2 to Rule 3.28 of the Listing Rules) as a company secretary; and
- (c) why the directors consider the individual to be suitable to act as the issuer’s company secretary.

Further, pursuant to Chapter 3.10 of the Guide, such waiver, if granted, will be for a fixed period of time (the “**Waiver Period**”) and on the following conditions:

- (a) the proposed company secretary must be assisted by a person who possesses the qualifications or experience as required under Rule 3.28 of the Listing Rules and is appointed as a joint company secretary throughout the Waiver Period; and
- (b) the waiver can be revoked if there are material breaches of the Listing Rules by the issuer.

Our Company has appointed Ms. Guo Ting (郭婷) (“**Ms. Guo**”), our secretary of the Board, as one of our joint company secretaries. She has extensive experience in board and corporate management matters but presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules. Therefore, we have appointed Ms. Au, an associate member of The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom, who fully meets the requirements stipulated under Rules 3.28 and 8.17 of the Listing Rules to act as the other joint company secretary and to provide assistance to Ms. Guo for an initial period of three years from the [REDACTED] to enable Ms. Guo to acquire the “relevant experience” under Note 2 to Rule 3.28 of the Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the Listing Rules.

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Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Ms. Guo may be appointed as a joint company secretary of our Company.

Given Ms. Au's professional qualification and experience, she will be able to explain to both Ms. Guo and the Company the relevant requirements under the Listing Rules and other applicable Hong Kong laws and regulations. Ms. Au will also assist Ms. Guo in organizing Board meetings and Shareholders' meetings of the Company as well as other matters of the Company which are incidental to the duties of a company secretary. Ms. Au is expected to work closely with Ms. Guo and will maintain regular contact with Ms. Guo, the Directors and the senior management of the Company.

Ms. Guo will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules to enhance her knowledge of the Listing Rules during the three-year period from the [REDACTED].

The Company will further ensure that Ms. Guo has access to the relevant training, support and advice from the compliance adviser (appointed by the Company pursuant to Rule 3A.19 of the Listing Rules) and the Company's legal adviser which will provide the Company and its joint company secretaries with professional advice and guidance on continuing obligations under the Listing Rules and compliance with applicable laws and regulations.

The waiver is valid for an initial period of three years from the [REDACTED]. Pursuant to paragraph 13 of Chapter 3.10 of the Guide for New Listing Applicants, the waiver requested in this submission shall be granted on two conditions: (i) Ms. Guo must be assisted by Ms. Au, who possesses the qualifications and experience required under Rule 3.28 of the Listing Rules and is appointed as a joint company secretary throughout the Waiver Period; and (ii) the waiver shall be valid for a period of three years from the [REDACTED] and will be revoked immediately if and when Ms. Au ceases to provide such assistance to Ms. Guo as a joint company secretary or if there are material breaches of the Listing Rules by the Company.

Before the expiration of the initial three-year period, the qualifications of Ms. Guo will be re-evaluated to determine whether the requirements as stipulated in Rules 3.28 and 8.17 of the Listing Rules can be satisfied and whether the need for ongoing assistance will continue. We will liaise with the Hong Kong Stock Exchange to enable it to assess whether Ms. Guo, having benefited from the assistance of Ms. Au for the preceding three years, will have acquired the skills necessary to carry out the duties of a company secretary and the relevant experience within the meaning of Note 2 to Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

EXEMPTION FROM COMPLIANCE WITH SECTION 342(1)(b) OF THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE AND PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all documents to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance and set out the reports specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

Paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires a company to include in its document a statement as to the gross trading income or sales turnover (as the case may be) of the company during each of the three financial years immediately preceding the issue of the document, including an explanation of the method used for the computation of such income or turnover and a reasonable breakdown between the more important trading activities.

Paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance further requires a company to include in its document a report by the auditors of the company with respect to (i) the profits and losses of the company for each of three financial years immediately preceding the issue of the document and (ii) the assets and liabilities of the company of each of the three financial years immediately preceding the issue of the document.

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from the compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interest of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or would otherwise be unnecessary or inappropriate.

Rule 4.04(1) of the Listing Rules requires that the consolidated results of the issuer and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the [REDACTED] document be included in the accountants' report to this document.

Rule 18A.03(3) of the Listing Rules requires that a biotech company must have been in operation in its current line of business for at least two financial years prior to [REDACTED] under substantially the same management. Rule 18A.06 of the Listing Rules requires that a biotech company must comply with Rule 4.04 of the Listing Rules modified so that references to "three financial years" or "three years" in Rule 4.04 shall instead be references to "two

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND
EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

financial years" or "two years", as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the [REDACTED] document.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants' Report is prepared to cover the financial years ended December 31, 2023 and 2024.

As such, the Sole Sponsor has applied, on behalf of our Company, to the SFC for a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of the accountants' report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (a) our Company is primarily engaged in the research and development, application and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] required under Chapter 18A of the Listing Rules;
- (b) the Accountants' Report for each of the years ended December 31, 2023 and 2024 [has been prepared] and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) given that our Company is only required to disclose its financial results for each of the financial years ended December 31, 2023 and 2024 in accordance with Chapter 18A of the Listing Rules and preparation of the financial results for the year ended December 31, 2022 would require additional work to be performed by our Company and our auditors, strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule would be unduly burdensome for our Company;
- (d) notwithstanding that the financial results [set out] in this document are only for the financial years ended December 31, 2023 and 2024 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; and

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

- (e) the Accountants’ Report covering the financial years [ended December 31, 2023 and 2024] (as set out in Appendix I to this document), together with other disclosures in this document, has already provided adequate and reasonable up-to-date information in the circumstances for the potential [REDACTED] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects and to form a view on the track record of our Company. Therefore, the exemption would not prejudice the interest of the [REDACTED].

The SFC [has granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the conditions that particulars of the exemption are set out in this document and that this document will be issued on or before [REDACTED].

NO-EXEMPT CONTINUING CONNECTED TRANSACTION

We have entered into and will continue to engage in certain transactions which would constitute continuing connected transactions for our Company under the Listing Rules upon [REDACTED]. We have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, certain waivers from strict compliance with certain requirements set out in Chapter 14A of the Listing Rules for such continuing connected transaction. For details, see “Connected Transactions” in this document.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Dr. Tian Guanghui (田廣輝)	Building 41, Yinshan Lakeview Garden Guoxiang Street Wuzhong Economic Development Zone Suzhou City, Jiangsu Province PRC	Chinese
Dr. Hu Tianwen (胡天文)	No. 7, Lane 699 Hesha Road, Hangtou Town Pudong New District Shanghai PRC	Chinese
Non-executive Director		
Mr. Liu Haoxuan (劉浩軒)	No. 61 Wanshou Road Haidian District Beijing PRC	Chinese
Independent Non-executive Directors		
Dr. Ju Dianwen (鞠佃文)	No. 13 Lane 871 Xiangyin Road, Yangpu District Shanghai PRC	Chinese
Ms. Cao Xinwen (曹新文)	No. 90, Lane 56 Guoquan Road, Yangpu District Shanghai PRC	Chinese
Dr. Xu Hongxi (徐宏喜)	Court B, Tower 2 Dragons Range 33 Lai Ping Road Shatin, New Territories Hong Kong	Chinese (Hong Kong)

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

SUPERVISORS

Name	Address	Nationality
Dr. Yang Rulei (楊汝磊)	Building 21, Jindian Garden No. 1233 Dongfang Avenue Suzhou City, Jiangsu Province PRC	Chinese
Mr. Zhou Hongju (周洪舉)	Building 62 Tonghu Street Tongzhou District Beijing PRC	Chinese
Mr. Li Jian (李建)	Block 18, Shunchi Phoenix Garden Suzhou Industrial Park Suzhou City, Jiangsu Province PRC	Chinese

For further details regarding our Directors and Supervisors, see “Directors, Supervisors and Senior Management” in this document.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Sole Sponsor

CITIC Securities (Hong Kong) Limited
18/F, One Pacific Place
88 Queensway
Hong Kong

[REDACTED]

Legal Advisors to our Company

as to Hong Kong and U.S. laws:

O'Melveny & Myers
31/F, AIA Central
1 Connaught Road Central
Hong Kong

as to PRC law:

JunHe LLP
26/F, HKRI Centre 1
HKRI Taikoo Hui
288 Shimen Road (No. 1)
Shanghai 200041, PRC

as to PRC intellectual property laws:

Jingtian & Gongcheng
34/F, Tower 3
China Central Place
77 Jianguo Road
Beijing, PRC

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

**Legal Advisors to the Sole Sponsor and
the [REDACTED]**

as to Hong Kong and U.S. laws:

Sullivan & Cromwell (Hong Kong) LLP
20/F, Alexandra House
18 Chater Road, Central
Hong Kong

as to PRC law:

King & Wood Mallesons
17/F, One ICC
Shanghai ICC 999 Huai Hai Road (M)
Shanghai 200030, the PRC

**Reporting Accountant and Independent
Auditor**

Deloitte Touche Tohmatsu
Certified Public Accountants
Registered Public Interest Entity Auditor
35/F, One Pacific Place
88 Queensway
Hong Kong

Industry Consultant

**China Insights Industry
Consultancy Limited**
10/F, Block B, Jing’an International Center
88 Puji Road, Jing’an District
Shanghai, PRC

Compliance Advisor

Somerley Capital Limited
20/F, China Building
29 Queen’s Road Central
Hong Kong

Independent property valuer

AVISTA Valuation Advisory Limited
Suites 2401-06, 24/F, Everbright Centre
108 Gloucester Road
Wan Chai, Hong Kong

[REDACTED]

CORPORATE INFORMATION

Head Office, Registered Office and Principal Place of Business in the PRC	8th Floor, Building A No. 108, Yuxin Road Suzhou Industrial Park District Suzhou, PRC
Principal Place of Business in Hong Kong	31/F, Tower Two, Times Square 1 Matheson Street Causeway Bay, Hong Kong
Company’s Website	<u>www.vigonvita.cn</u> <i>(Information contained in this website does not form part of this document)</i>
Joint Company Secretaries	Ms. Guo Ting (郭婷) 606 E’shan Road Pudong New District Shanghai, PRC Ms. Au Wing Sze (區詠詩) (ACG and HKACG) 31/F, Tower Two, Times Square 1 Matheson Street Causeway Bay Hong Kong
Authorized Representatives	Dr. Tian Guanghui (田廣輝) Building 41, Yinshan Lakeview Garden Guoxiang Street Wuzhong Economic Development Zone Suzhou City, Jiangsu Province PRC Ms. Au Wing Sze (ACG and HKACG) 31/F, Tower Two, Times Square 1 Matheson Street Causeway Bay Hong Kong
Audit Committee	Ms. Cao Xinwen (<i>Chairperson</i>) Dr. Xu Hongxi Dr. Ju Dianwen

CORPORATE INFORMATION

Remuneration and Appraisal Committee Dr. Xu Hongxi (*Chairperson*)
Dr. Hu Tianwen
Dr. Ju Dianwen

Nomination Committee Dr. Tian Guanghui (*Chairperson*)
Dr. Xu Hongxi
Ms. Cao Xinwen

[REDACTED]

Principal Banker **China Construction Bank**
(Suzhou Industrial Zone Branch)
122 Wangdun Road
Suzhou Industrial Zone District
Suzhou, PRC

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from official government publications, available sources from public market research and other sources from independent suppliers. In addition, we engaged China Insights Industry Consultancy Limited, or CIC, to prepare an independent industry report, or the CIC Report, for the [REDACTED]. The information from official government sources have not been independently verified by us, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors, officers, employees, advisers and agents or any other persons or parties involved in the [REDACTED], except for CIC, and no representation is given as to its accuracy. Accordingly, the information from official and non-official sources contained herein may not be accurate and should not be unduly relied upon.

GLOBAL AND CHINA PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is a crucial component of the economy. According to CIC, the size of global pharmaceutical market increased from US\$1,239.0 billion in 2018 to US\$1,569.6 billion in 2023 with a CAGR of 4.8%, and is expected to reach US\$2,410.0 billion in 2035, representing a CAGR of 3.6% from 2023 to 2035. The size of pharmaceutical market in China increased from RMB1,551.2 billion in 2018 to RMB1,763.9 billion in 2023 with a CAGR of 2.6%, and is expected to reach RMB3,683.9 billion in 2035, representing a CAGR of 6.3% from 2023 to 2035.

In the pharmaceutical industry, small molecules and biologics represent two distinct categories of drugs, with small molecule drugs playing a significant role in drug development today. The small molecule drugs can target both cell surface and intracellular sites, expanding the range of potential drug targets. Additionally, from a patient convenience perspective, oral small molecules enhance accessibility and improve patient compliance by reducing the need for frequent hospital visits, thereby conserving medical resources and lowering treatment costs.

Small molecule drugs can be categorized into brand-name and generic drugs. When a new drug is introduced, it is patented and sold under a brand name. Once the patent expires, other companies may produce and sell generic versions of the drug. Although generics may differ slightly from the brand-name version, they must demonstrate similar efficacy. Both brand-name and generic drugs play crucial roles in public health, with brand-name drugs often representing innovative treatments that address unmet medical needs, while generics offer more affordable alternatives, enhancing accessibility and reducing healthcare costs without compromising effectiveness. Together, they contribute to a well-balanced and accessible healthcare system.

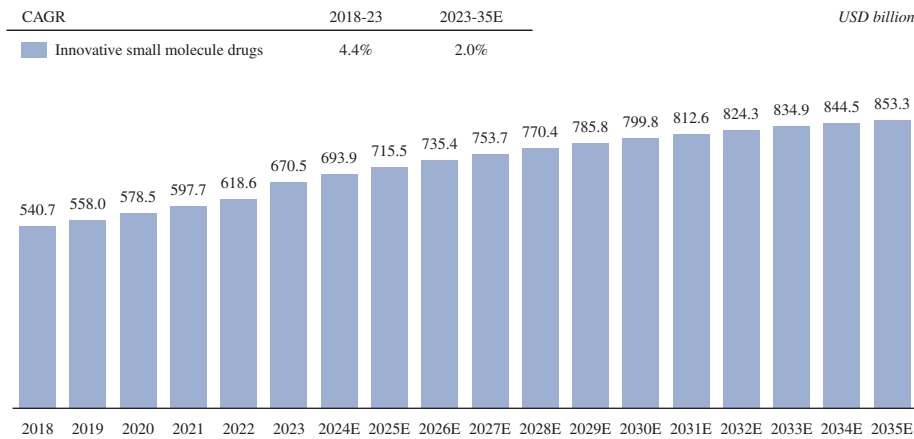
INDUSTRY OVERVIEW

INNOVATIVE SMALL MOLECULE DRUG INDUSTRY

Innovative small molecules are at the forefront of drug development due to their versatility and effectiveness in treating a wide range of conditions, from infectious diseases and cancer to neuropsychiatric and reproductive disorders. They represent the most widely approved drug class, with 30 approved small molecule drugs in the U.S. in 2023, accounting for 55% of all approved drugs, and 48 approved small molecule drugs in China in 2023, accounting for 59% of all approved drugs.

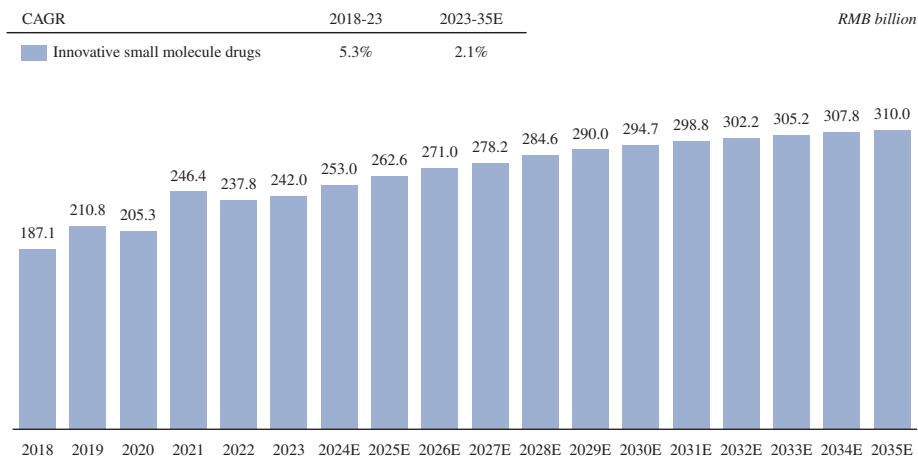
As a result, the global market for innovative small molecule drugs has experienced significant growth, increasing from US\$540.7 billion in 2018 to US\$670.5 billion in 2023, representing a CAGR of 4.4%. The market is expected to reach US\$853.3 billion by 2035, reflecting a CAGR of 2.0% from 2023 to 2035. Similarly, the innovative small molecule drugs market in China has steadily expanded, growing from RMB187.1 billion in 2018 to RMB242.0 billion in 2023, at a CAGR of 5.3%. It is projected to continue growing at a CAGR of 2.1% from 2023 to 2035, reaching RMB310.0 billion by 2035.

Historical and Forecasted Global Market Size of Innovative Small Molecule Drugs, 2018-2035E



Source: WHO, China Insights Consultancy

Historical and Forecasted Market Size of Innovative Small Molecule Drugs in China, 2018-2035E

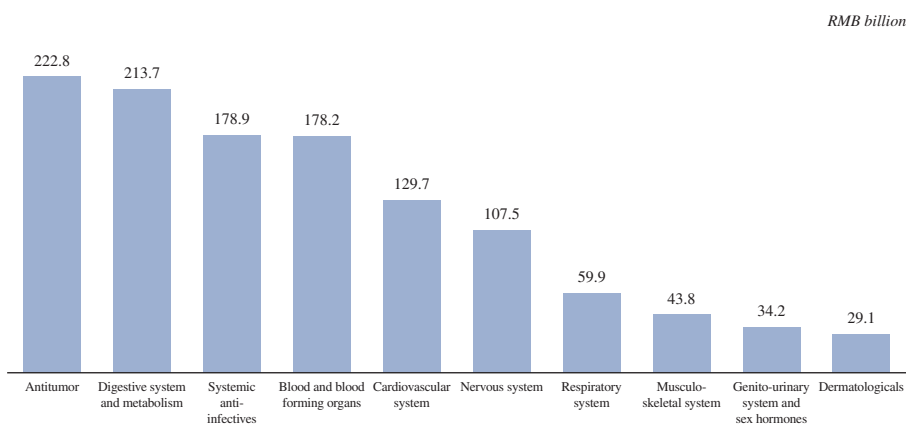


Source: National Bureau of Statistics, NHC, China Insights Consultancy

INDUSTRY OVERVIEW

Antiviral, neuropsychiatric, and reproductive health drugs are important segments of the pharmaceutical industry in China. According to CIC, the systemic anti-infectives market ranked third in terms of sales, with a value of RMB178.9 billion in 2023, highlighting the critical importance of infectious disease prevention and treatment. Antiviral drugs, which target widespread and potentially life-threatening diseases, constitute an important portion of this market. Neuropsychiatric drugs, driven by a large patient population and high treatment demand, ranked sixth in sales, generating RMB107.5 billion in 2023. While the market for reproductive health drugs is comparatively smaller, it holds significant growth potential fueled by increasing public health awareness and improving living standards.

Top Ten Therapeutic Areas in China, 2023



Notes:

1. Systemic anti-infectives include systemic antiviral drugs, systemic antibacterial drugs, immune sera and immunoglobulins, systemic antifungal drugs and vaccines.
2. In this context, “Nervous system” refers to “Neuropsychiatric drugs”, while “Genito-urinary system and sex hormones” corresponds to “Reproductive health drugs.”

Source: National Bureau of Statistics, NHC, China Insights Consultancy

Growth Drivers and Future Trends

The growth of the innovative small molecule drug market is driven by several key factors. Technological advancements, particularly breakthroughs in biotechnology, genomics, and molecular biology, are enabling the development of more targeted, precise, and personalized therapies. At the same time, increased investments are focused on identifying new therapeutic targets and improving existing treatments, further advancing the development of breakthrough medicines. Collaboration between pharmaceutical companies, academic institutions, and technical organizations is also vital, as the sharing of expertise and resources accelerates the drug discovery and development process. Additionally, the demand for new therapies is being fueled by unmet clinical needs, particularly for diseases with limited treatment options. For example, the emergence of new diseases, such as COVID-19 and antibiotic-resistant infections, as well as the rising prevalence of chronic conditions such as neuropsychiatric disorders, is driving the need for novel treatments.

INDUSTRY OVERVIEW

Entry Barriers

New entrants in the innovative drug development market face several significant barriers. First, technological and expertise gaps can be a major obstacle for startup companies, as advanced knowledge in molecular biology, chemistry, and clinical development is essential, and larger, established players typically have the resources and skilled personnel needed to navigate these complexities. In the realm of antiviral therapies, rapid viral mutations, the emergence of drug resistance, and the need to selectively eliminate viruses without damaging human cells further complicate development efforts. In addition, finding suitable animal models for antiviral drug evaluation is challenging, and the outcomes observed in animal models can often differ significantly from those seen in humans. Also, drug development for neuropsychiatric disorders also faces several challenges. The inherent complexity of the pathogenesis of neuropsychiatric disorders, combined with the challenge of achieving effective drug penetration across the blood-brain barrier, poses significant obstacles to treatment development. Furthermore, different neuropsychiatric disorders present unique therapeutic challenges: antidepressants struggle with slow onset of action and substantial placebo effects; antiepileptic drugs must precisely target abnormal neuronal activity while minimizing severe side effects; and antipsychotic drugs require careful balancing of efficacy with adverse effects, such as metabolic syndrome. Together, these challenges result in difficulties in drug discovery and extended development timelines.

Moreover, the high capital investment required for drug discovery, preclinical testing, clinical trials, and regulatory approval creates a financial challenge, especially for smaller companies. Intellectual property protections, such as patents, data exclusivity, and trade secrets, further hinder new entrants by safeguarding the competitive edge of established players. Finally, the clinical trials process is complex and costly, with difficulties in recruiting patients for large-scale, multi-phase trials, particularly for rare diseases or specific patient populations, which can cause delays in development timelines.

Antiviral Drugs

A virus is a pathogen that relies entirely on living host cells to replicate, as it cannot carry out life processes independently. It invades an organism using an infection mechanism and hijacks the host’s cellular machinery to produce new viral particles. Drugs targeting viral infection are critically needed due to the rapid spread of viruses and their high mutation rates, which enable them to evade treatment, disrupt normal life, and cause societal panic. The global antiviral drug market was valued at US\$94.2 billion in 2023 and is projected to remain relatively stable, reaching US\$97.4 billion by 2035, with a CAGR of 0.3% from 2023 to 2035. In China, the antiviral drug market was valued at RMB24.9 billion in 2023 and is expected to reach RMB44.9 billion by 2035, growing at a CAGR of 5.0% from 2023 to 2035.

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Structurally, a virus consists of nucleic acid, either DNA or RNA, encased in a protective protein shell. Viral replication differs depending on the type of nucleic acid. DNA viruses, typically double-stranded, replicate within the cell nucleus, leveraging the host’s replication and transcription systems. In contrast, RNA viruses, which are usually single-stranded, replicate predominantly in the cytoplasm. Due to the high error rate during RNA replication, RNA viruses exhibit greater genetic variability compared to DNA viruses, making them more prone to mutations and increasing their potential to cause antiviral drug resistance. Studies indicate that RNA viruses have a higher mutation rate compared to DNA viruses, leading to their rapid evolution and greater adaptability to changing environments. This high variability underscores the need for accelerated drug development to effectively combat RNA virus infections.

RNA viruses rely on RdRp for their replication. RdRp is a viral enzyme that synthesizes RNA from an RNA template, facilitating the replication of viral genomes and transcription of structural proteins necessary for virus proliferation. This enzyme operates without a counterpart in mammalian cells. Furthermore, considering that RdRp is essential for RNA virus replication and is highly conserved, it serves as an excellent therapeutic target for antiviral drug development. By targeting RdRp, the replication of RNA viruses, such as those causing influenza, hepatitis C, and emergent diseases such as MERS and SARS, can be effectively disrupted, reducing their ability to propagate and cause disease.

Among RdRp inhibitors, nucleoside analog inhibitors, including VV116, are particularly effective. These compounds mimic natural nucleosides, allowing their incorporation into the growing RNA strand during replication. Once incorporated, nucleoside analog inhibitors either terminate the viral DNA or RNA extension or induces lethal mutations to viral genome, resulting in robust antiviral effects. Furthermore, nucleoside analog inhibitors exhibit broad-spectrum antiviral activity due to the conserved nature of RdRp across RNA viruses. These properties position nucleoside analog inhibitors as a cornerstone in antiviral drug development, addressing the challenges posed by RNA virus infections.

RSV Drugs

RSV is a non-segmented, negative-sense, single-stranded RNA virus that primarily spreads through hands, fomites, and aerosols. The global prevalence of RSV is expected to increase from 136.2 million in 2023 to 157.0 million in 2035, with a CAGR of 1.2%. In China, the prevalence is forecasted to rise from 25.5 million in 2023 to 26.2 million in 2035, with a CAGR of 0.2%. Infants and young children are the primary victims of RSV infection, with 50-70% being infected in their first year of life and 90% in their second year. In China, infants and young children aged one to 24 months account for approximately 30.6% of the RSV patient population in 2023.

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RSV treatment drugs are of major clinical needs. Although RSV vaccines and prophylactic treatments can reduce the incidence of infections, they do not guarantee complete immunity, and reinfections are common throughout life. RSV infections can range from mild to severe, particularly in vulnerable populations such as premature infants, the elderly, and immunocompromised individuals, who may experience severe complications such as bronchiolitis or pneumonia. Studies indicate that the global hospitalization rate for RSV-related diseases in children aged five years and younger is approximately 1.7%, with an in-hospital mortality rate of around 0.5%. Among older adults (≥ 65 years), the hospitalization rate ranges from 15% to 25%, while the in-hospital mortality rate is estimated at 6% to 8% worldwide.

While preventive measures reduce the risk of infection, they cannot eliminate severe cases, and treatment options remain essential to manage complications, reduce hospitalization, and prevent mortality. Additionally, vaccines and monoclonal antibodies have limitations in accessibility, cost, and population coverage, leaving some individuals without preventive therapies. The mutagenicity of RSV also leads to the emergence of new variants, which may evade immunity from previous infections or vaccines, necessitating new treatments. Given that RSV infection cannot be prevented by long-term immunity, repeated treatments are needed for managing recurrent infections throughout life.

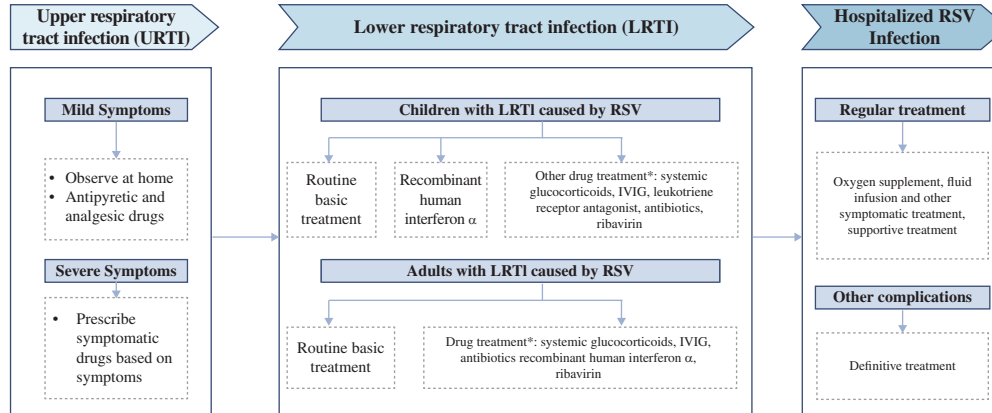
For infants and young children who are infected with RSV, capsules and tablets are generally not suitable for direct use. Dosage forms that can be safely swallowed, such as dry suspensions or liquids, are preferred for this age group. A dry suspension offers a practical and patient-friendly solution for these groups. By ensuring accurate dosing and enhancing compliance, dry suspensions provide a more effective method of medication delivery. This approach can potentially improve treatment outcomes and expand access to RSV therapeutics.

Treatment Paradigm

Currently, the standard treatment for RSV is primarily supportive care, including oxygen supplementation, nasal decongestants, hydration, and nutrition, along with the use of bronchodilators, epinephrine, and steroids. For pediatric RSV infections, clinical treatment options include interferon, ribavirin, and bronchodilators, though routine use of ribavirin is not recommended due to significant side effects and insufficient evidence supporting its efficacy in treating RSV. In adults, treatment for RSV infection is largely confined to supportive care, such as bronchodilators, supplemental oxygen, intravenous infusions, and antipyretics.

INDUSTRY OVERVIEW

Treatment Paradigm of RSV in Different Susceptible Population in China



Abbreviations: IVIG = intravenous immunoglobulin.

Note:

* None of the drug treatments are recommended for adults. Additionally, except for recombinant human interferon α , all other drug treatments are not recommended for children.

Source: AAP, *Expert Consensus on the Diagnosis, Treatment, and Prevention of Respiratory Syncytial Virus Infection in Children (2023 Edition)* (《兒童呼吸道合胞病毒感染診斷、治療和預防專家共識(2023版)》) and *Guidelines for the Treatment and Prevention of Lower Respiratory Tract Infections Caused by Human Respiratory Syncytial Virus (2024 Edition)* (《人呼吸道合胞病毒下呼吸道感染治療及預防指南(2024版)》), China Insights Consultancy

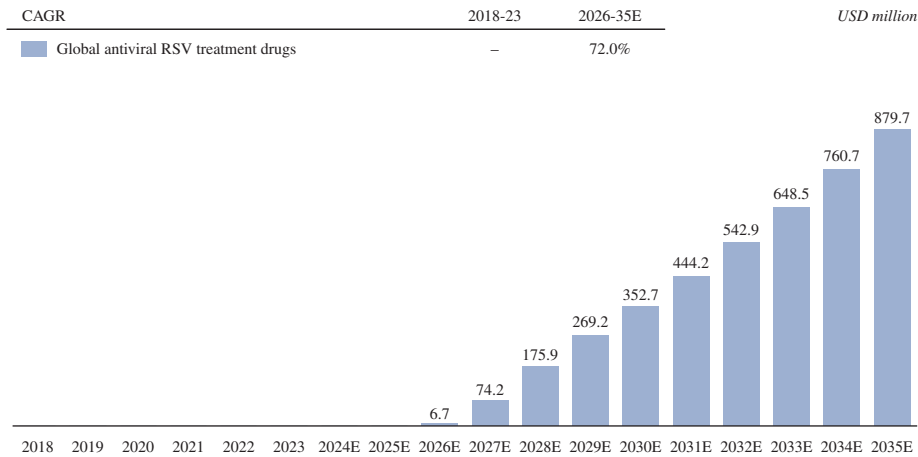
However, according to the latest Guidelines for the Treatment and Prevention of Lower Respiratory Tract Infections Caused by Human Respiratory Syncytial Virus (2024 Edition), the efficacy of antiviral drugs such as ribavirin remains unclear, and their potential side effects make them unsuitable for routine use. Additionally, medications like corticosteroids and bronchodilators have limited effectiveness in treatment and should be used with caution. Therefore, there is an urgent need for innovative therapeutic options to treat RSV infections.

Market Size

The development of small molecule antiviral products for RSV treatment represents a significant unmet medical need on a global scale. However, as of the Latest Practicable Date, no small molecule antiviral products for RSV treatment were available worldwide. With the approval of the first innovative small molecule antiviral therapy anticipated in 2026, the global market is expected to reach US\$6.7 million in 2026 and grow substantially to US\$879.7 million by 2035 with a CAGR of 72.0% from 2026 to 2035.

INDUSTRY OVERVIEW

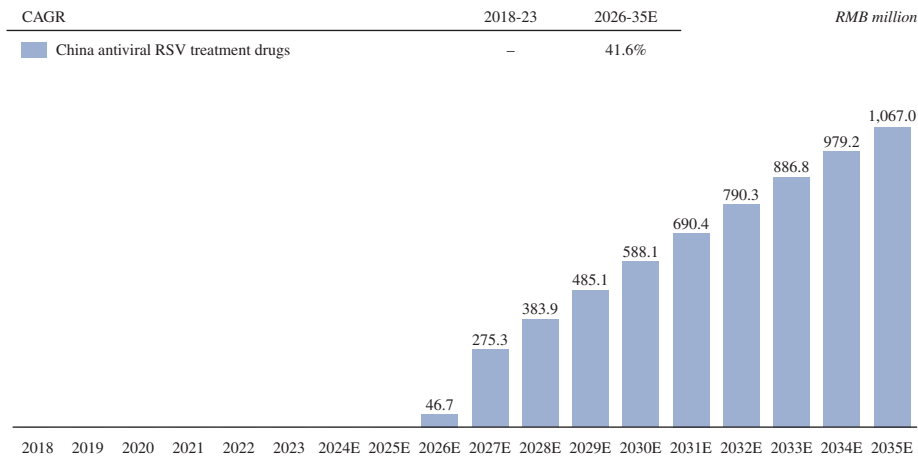
Historical and Forecasted Global Market Size of Antiviral Therapy for RSV Treatment, 2018-2035E



Source: UN, The Lancet, The Journal of Infectious Diseases, China Insights Consultancy

Similarly, in China, there were no small molecule antiviral products approved for RSV treatment as of the Latest Practicable Date. However, with the anticipated approval of the first innovative small molecule antiviral drug in 2026, the market for small molecule antiviral therapy for RSV treatment in China is expected to reach RMB46.7 million in 2026, growing substantially to RMB1,067.0 million by 2035 with a CAGR of 41.6% from 2026 to 2035.

Historical and Forecasted Market Size of Antiviral Therapy for RSV Treatment in China, 2018-2035E



Source: The Journal of Infectious Diseases, Journal of Clinical Pediatrics, China Insights Consultancy

INDUSTRY OVERVIEW

Competitive Landscape

As of the Latest Practicable Date, no innovative small molecule antiviral therapies had been approved on a global scale for the treatment of RSV. Globally, six small molecule antiviral drug candidates were under development for RSV treatment.

In China, two small molecule antiviral drug candidates were in development for RSV treatment. Among these products, VV116 was the only candidate targeting RdRp. VV116 dry suspension also stood out as the only dry suspension formulation designed for convenient administration to infants and young children, which was in a Phase II/III clinical trial as of the Latest Practicable Date.

Global Competitive Landscape of Small Molecule Antiviral Drug for RSV Treatment

Candidate	Formulation	MoA	Company	Clinical phase	Study Location	First posted date	Indication
AK0529	Enteric capsules	F protein	Ark Biopharmaceutical	III	China	2024/03/12	RSV for children
VV116	Dry Suspension	RdRp	the Company	II/III	China	2024/01/23	RSV for children
EDP-938	Tablets	N protein	Enanta	Ib	U.S.	2022/10/06	RSV for adults
AK0529	Enteric capsules	F protein	Ark Biopharmaceutical	II	China	2018/12/13	RSV for adults
EDP-938	Tablets	N protein	Enanta	II	U.S.	2021/03/25	RSV for children
EDP-323	Oral administration	RdRp (L protein)	Enanta	Ia	U.S.	2023/12/14	RSV for adults
GS-5245	Oral administration	RdRp	Gilead Sciences	II	U.S.	2024/09/05	RSV for adults
VV116	Dry Suspension	RdRp	the Company	I	China	2024/03/22	RSV for adults
S-337395	Injection	RdRp (L protein)	Shionogi/UBE Corporation	I	U.S.	2024/02/21	RSV for adults

Abbreviations: RdRp = RNA-dependent RNA polymerase; IFN = interferon.

Notes: The clinical trial of EDP-938 for the treatment of adult patients with RSV in the U.S. failed to meet the primary endpoint.

Source: ClinicalTrials.gov, CDE, China Insights Consultancy

COVID-19 Drugs

SARS-CoV-2, which caused the COVID-19 pandemic, is a positive-sense, single-stranded RNA virus that primarily affects the respiratory system, causing flu-like symptoms such as cough, fever, muscle pain, and difficulty in breathing. According to the WHO, there were more than 700 million cases of COVID-19 worldwide from its outbreak until 2024. Research indicates that the large-scale emergence of the COVID-19 pandemic has had a profound impact on the global economy and society, particularly in the early stages, when healthcare systems in many countries were overwhelmed by the surge in cases. This led to shortages of medical resources and delays in providing timely treatment to patients.

INDUSTRY OVERVIEW

COVID-19 treatments worldwide fall into two main categories: large molecule neutralizing antibodies targeting the spike protein and small molecule drugs that inhibit viral replication. While neutralizing antibodies are costly, administered via injection, and often ineffective against variants like Omicron, small molecule drugs provide better clinical outcomes, affordability, and ease of administration through oral formulations. These advantages contribute to the broader adoption of small molecules among patients.

Currently, the recommended antiviral treatment of COVID-19 is still small molecule drugs. Antiviral medications, include nirmatrelvir and remdesivir, are administered to inhibit viral replication and reduce viral load. Severe cases may require a combination of antiviral drugs, corticosteroids, and immunomodulators like IL-6 inhibitors or baricitinib to manage inflammation and prevent cytokine storms. These treatments provide a multi-faceted approach to combating the disease. However, current COVID-19 treatments face limitations in efficacy, side effect risks, drug resistance, unequal access, and high costs. Additionally, viral mutations, individual variability, and complex immune responses further complicate effective treatment.

As of the Latest Practicable Date, 10 small molecule antiviral drugs had been fully approved or conditionally approved globally for COVID-19 treatment, and two fully approved for marketing in China. VV116 was the only product that has gained full marketing approval both in China and internationally. In 2023, Veklury (remdesivir) led the global market, while Paxlovid dominated the Chinese market with a 58% share. Together with other top products, the leading players accounted for nearly 100% of the sales in 2023, highlighting the concentrated nature of the competitive landscape.

Severe Fever with Thrombocytopenia Syndrome Virus Drugs

SFTSV is a segmented, negative-strand RNA virus. Its genome encodes RdRp to facilitate viral replication and transcription. The virus primarily targets human lymph nodes, leading to lymphadenopathy and necrotizing lymphadenitis, and rapidly replicates in the lymph nodes and spleen after entering systemic circulation, resulting in viremia. This triggers immune dysfunction, cytokine storms, endothelial damage, and, in severe cases, death due to bleeding or multiple organ failure.




According to The Lancet in 2024, the overall pooled infection rate of SFTSV was 18.94 per ten million people. SFTSV can be life-threatening, with an estimated case fatality rate of approximately 7.8%. Reports indicate that SFTSV is associated with a high mortality rate of up to 44.7% in cases involving organ failure and central nervous system complications, with mortality rates exceeding 20% in Japan and South Korea. Developing a treatment for SFTSV is crucial for society, as it addresses a pressing medical need for a disease currently lacking effective therapeutic options. The spread of SFTSV poses public health risks, often leading to societal and familial anxiety due to its potential to cause outbreaks.

INDUSTRY OVERVIEW

Treatment Paradigm

Currently, general treatment of SFTSV focuses on symptom management, emphasizing lifestyle adjustments, including balanced nutrition, regular exercise, mental health support, and basic health monitoring. Complications treatment addresses specific medical issues arising from the condition, employing targeted therapies and specialized interventions. TCM offers a holistic alternative, utilizing herbal remedies, acupuncture, and balance-focused practices to enhance the body’s internal harmony. Nevertheless, as of the Latest Practicable Date, there was no antiviral drug for SFTSV, and existing treatments were mainly symptomatic supportive treatment and treatment for complications. Therefore, there is a significant medical need for developing antiviral drugs for SFTSV treatment.

Treatment Paradigm of SFTSV in China

General treatment 	<ol style="list-style-type: none">1. Nutritional support therapy. Rest in bed, give easily digestible, nutritious semi-liquid or soft food, ensure caloric supply and maintain water, electrolyte and acid-based balance.2. Physical cooling is given to patients with fever, and drugs can be used to reduce fever when the fever is high.3. Plasma and platelets can be transfused for patients with obvious bleeding or significantly reduced platelet count (such as less than $20 \times 10^9/L$).4. For severe and critical patients with progressive deterioration of the condition and over-activation of the body's inflammatory response, glucocorticoids should be used early and short-term as appropriate.5. Severe and critical cases should be transferred to the ICU for treatment.6. Antiviral treatment: Ribavirin (use with caution), Favipiravir (patients with low viral load), calcium channel blockers (Benidipine Hydrochloride and Nifedipine have a certain inhibitory effect)7. Glucocorticoids are not recommended as a routine treatment for SFTS
Complications treatment 	<ol style="list-style-type: none">1. Viral myocarditis. Rest in bed and strengthen monitoring; control the intake and output, and avoid excessive fluid load; give coenzyme Q10, vitamin C and other nutritional myocardial treatments.2. Encephalitis. Give symptomatic comprehensive treatment such as mannitol to reduce intracranial pressure; pay attention to airway protection and give mechanical ventilation when necessary.3. Secondary bacterial and fungal infections. For those who are considered to have secondary bacterial and fungal infections, antibacterial or fungal drugs can be given empirically, and the treatment plan can be adjusted according to the drug sensitivity results.
Traditional Chinese Medicine treatment 	<ol style="list-style-type: none">1. Mild. Recommended prescription: Yin Qiao San (銀翹散).2. Severe. Recommended Chinese patent medicine: Xue Bi Jing Injection (血必淨注射液).3. Recovery period. Recommended prescription: Zhu Ye Shi Gao Tang (連翹竹葉石膏湯).

Abbreviations: SFTS = severe fever with thrombocytopenia syndrome.

Sources: *Diagnosis and Treatment Plan for Fever with Thrombocytopenia Syndrome (2023 Edition)* (發熱伴血小板減少綜合徵診療方案(2023版)), *Expert Consensus on the Diagnosis and Treatment of Severe Fever with Thrombocytopenia Syndrome (2022)* (重症發熱伴血小板減少綜合徵診治專家共識(2022)), *China Insights Consultancy*

Competitive Landscape

As of the Latest Practicable Date, no drugs have been approved for the treatment of SFTSV in China. VV261 stood out as the first and only small molecule antiviral drug for SFTSV treatment in China, which was in the Phase I clinical stage.

INDUSTRY OVERVIEW

Competitive Landscape of Small Molecule Antiviral Drug for SFTSV Treatment in China

Candidate	MoA	Company	Clinical phase	First posted date	Indication
VV261	RdRp	the Company	I	2024/08/27	SFTSV

Sources: CDE, China Insights Consultancy

Neuropsychiatric Drugs

Neuropsychiatry focuses on psychiatric disorders related to brain dysfunction or the indirect effects of extracranial diseases, addressing affective, cognitive, and behavioral issues. Key conditions within the neuropsychiatric domain include depression, schizophrenia, epilepsy, bipolar disorder, Parkinson’s disease, and Alzheimer’s disease. These disorders can result from genetic, traumatic, or age-related factors, as well as external stressors such as life events, abuse, and substance use. Treatment typically combines medication with psychotherapy.

With advancements in diagnostic methods and the aging population, neuropsychiatric disorders have emerged as a significant global health challenge. According to WHO, worldwide, the number of individuals affected by these disorders was 3,497.2 million in 2023 and is projected to reach 3,997.0 million by 2035. In China, approximately 239.6 million individuals were affected in 2023, with this number expected to grow to 258.5 million by 2035. The global market for neuropsychiatric drugs was valued at US\$198.5 billion in 2023, with an expected growth to US\$254.0 billion by 2035. The market for neuropsychiatric drugs in China was valued at RMB 107.5 billion in 2023, and is projected to increase to RMB137.5 billion in 2035.

Current drug treatments for neuropsychiatric disorders face several significant challenges, with medication non-adherence being the most prominent. Issues including missed doses, underdosing, or premature discontinuation, significantly undermines treatment outcomes, prognosis, and functional recovery. This is especially concerning for chronic or lifelong conditions, as poor adherence leads to suboptimal symptom control, and diminished patient confidence in medications. Delayed onset, unreliable effects, and high recurrence rates are often cited as reasons why these treatments fail to meet patients’ therapeutic needs. Additionally, the complexity and heterogeneity of neuropsychiatric disorders make it difficult to identify effective therapeutic targets. Moreover, common side effects such as sedation, dizziness, and gastrointestinal issues further complicate treatment, negatively affecting patients’ daily lives and work, and further reducing adherence. These challenges highlight the need for safer and more effective therapies.

For medications designed to treat neuropsychiatric disorders, achieving a higher concentration in the brain while limiting distribution to peripheral tissues and organs is a key goal. Ensuring good blood-brain barrier permeability allows for effective treatment at lower doses, which helps reduce side effects and enhances patient adherence.

INDUSTRY OVERVIEW

Anti-depression Drugs

Depressive disorder refers to a group of mental disorders characterized by a dysphoric mood and a loss of interest and pleasure, with or without illusion, delusion, and agitation symptoms. The onset of depressive disorder may drive the patients to commit suicide. According to the clinical features, the disease can be categorized into major depressive disorder, seasonal mood disorder, perinatal depression, persistent depressive disorder, and depression with psychotic symptoms.

Depression is a common and dangerous condition affecting a large population and has become a major health issue. According to GBD2021, worldwide, the number of individuals affected by these disorders was 355.3 million in 2023 and is projected to reach 399.4 million in 2035. In China, approximately 50.4 million individuals were affected in 2023, with this number expected to grow to 53.1 million in 2035.

Rapid-onset treatment plays a crucial role in reducing suicide rates among individuals with depression. Traditional approaches often require weeks or months before demonstrating significant effects, leaving patients in a vulnerable state during the interim. Immediate intervention methods, such as fast-acting medications, can quickly address severe symptoms and stabilize at-risk individuals. While antidepressants are effective, one-third to half of individuals with depression do not respond to multiple antidepressants, and an even larger proportion may achieve only a partial response. Therefore, there is a pressing need to develop, evaluate, and better understand the effectiveness of new therapeutic agents or treatment modalities.

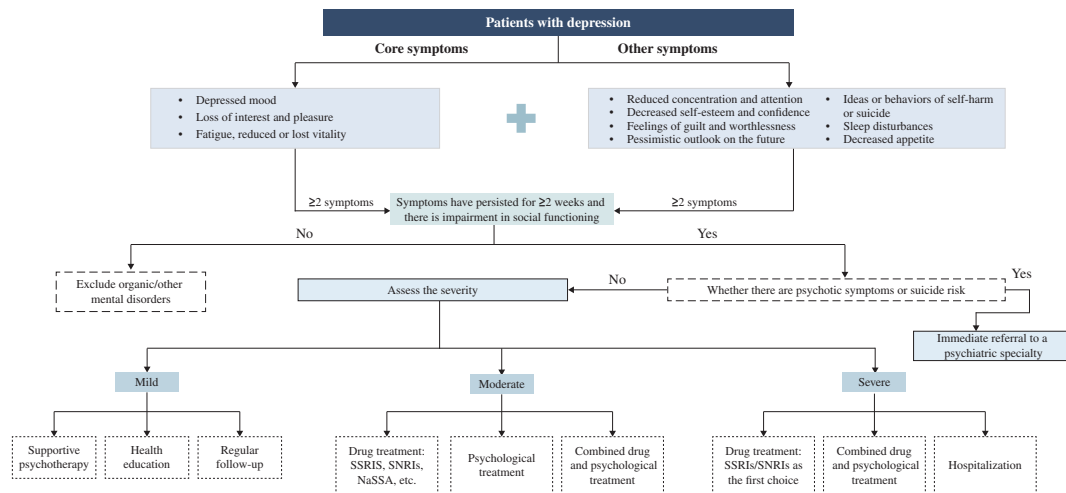
Treatment Paradigm

Depressive disorders can be treated based on their severity, categorized as mild, moderate, or severe. Mild cases may benefit from tailored interventions such as supportive psychotherapy, health education, and regular follow-up. Moderate to severe cases typically require pharmacological treatment, including SSRIs, SNRIs, or NaSSAs, with or without psychological therapy. For individuals at risk of suicide, immediate referral to a psychiatric specialist is strongly recommended.

Medication therapy is the primary treatment for depressive disorder, with various drugs approved to target neurotransmitter imbalances. First-line treatments, including escitalopram, are preferred due to their efficacy and safety in modulating 5-HT, norepinephrine, and dopamine levels. However, these drugs have notable limitations, including a delayed onset of action and a poor response in approximately 30-40% of patients undergoing first-line treatment. Second-line options, such as tricyclic antidepressants and tetracyclic antidepressants such as amitriptyline and clomipramine, are less favored due to safety concerns and poor patient compliance. Third-line treatment include monoamine oxidase inhibitors, though restricted by dietary limitations and safety issues, are used for patients who do not respond to first- and second-line treatments. Additionally, traditional Chinese medicines are approved for mild to moderate depression, and esketamine was approved for the treatment of depression in China, yet it can be abused for its hallucinogenic properties.

INDUSTRY OVERVIEW

Treatments of Depressive Disorder in China



Abbreviations: SSRIs = selective serotonin reuptake inhibitors; SNRIs = serotonin and norepinephrine reuptake inhibitors; NaSSA = noreadrenergic and specific serotonergic antidepressants.

Source: *Guidelines for Primary Care Diagnosis and Treatment of Depression (2021 Edition)* (抑鬱症基層診療指南 (2021年)), China Insights Consultancy

There is a significant unmet medical need in the development of antidepressants. Patients with depressive disorder often struggle with poor treatment adherence and high recurrence rates, with up to 40% failing to achieve full recovery, leading to recurring symptoms. Long-term therapy is crucial for a cure, but maintaining patient compliance remains a major challenge, with interruptions often contributing to relapse. Antidepressants are also associated with severe side effects, such as gastrointestinal issues, migraines, hypertension, and sexual dysfunction, with 86% of patients reporting at least one side effect, 55% of which are considered bothersome. These side effects create a psychological burden, further diminishing compliance and hindering overall prognosis. Additionally, while antidepressants typically take several days to show therapeutic effects, side effects emerge much sooner, intensifying patient distress.

Traditional antidepressants have a slow onset of action due to the low sensitivity of 5-HT receptors. Typically, these medications begin to show effects after about two weeks, and it takes four to six weeks for their full effects to become apparent. This delay can temporarily worsen symptoms and increase both the physical and psychological burden on patients. Reducing the onset time is crucial for improving patient compliance and enhancing the efficacy of antidepressants. By inhibiting 5-HT reuptake and targeting 5-HT receptors, these medications can potentially elevate 5-HT levels in the synaptic cleft, offering faster relief of depression-related symptoms, reducing the incidence and severity of gastrointestinal side effects, thereby increasing patient compliance. Unlike traditional treatments, novel antidepressants aim to more rapidly alter the level of neurotransmitter, enabling quicker therapeutic effects.

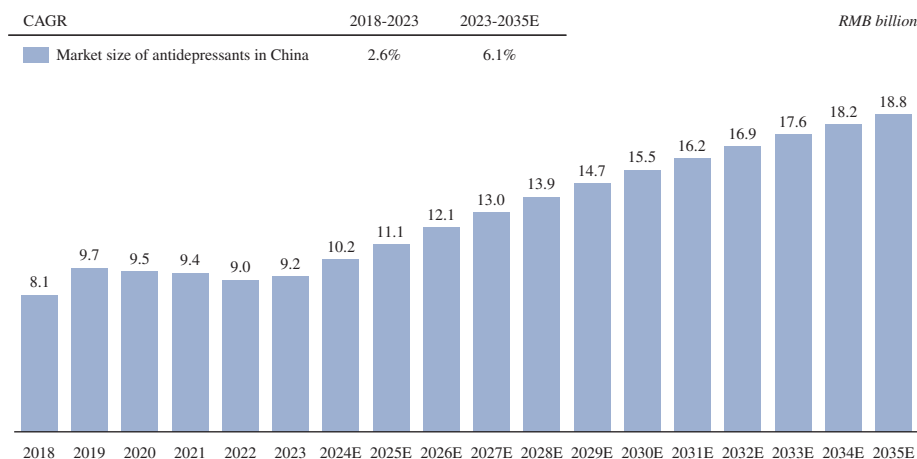
INDUSTRY OVERVIEW

While esketamine has the benefit of rapid onset, its association with abuse risk limits its suitability for long-term use. Esketamine is a controlled substance classified as a Schedule III drug under the DEA Controlled Substances Act. Beyond addressing abuse concerns, the safety profile of medications becomes especially critical for patients requiring extended treatment. This underscores the importance of striking a balance between safety and efficacy when selecting drug targets, ultimately fostering better patient adherence.

Market Size

The antidepressant market is projected to experience steady growth in the coming years. In China, the antidepressant market was valued at RMB8.1 billion in 2018, rising to RMB9.2 billion in 2023, reflecting a CAGR of 2.6% over the five-year period. It is anticipated to grow to RMB18.8 billion in 2035, at a CAGR of 6.1% from 2023 to 2035.

Historical and Forecasted Market Size of Drugs for Depressive Disorder in China, 2018-2035E



Note: During 2020-2023, the allocation of medical resources was impacted, particularly for the treatment of non-acute conditions. Additionally, while public awareness of mental health issues increased, market growth was hindered by disruptions in supply chains and challenges in accessing medical services during this period.

Source: Guideline for primary care of major depressive disorder, China Insights Consultancy

Competitive Landscape

As of the Latest Practicable Date, 24 innovative small molecule antidepressants had been approved for marketing in China. Additionally, there were 14 innovative small molecule antidepressants under Phase II or later stage clinical development in China. LV232, an inhibitor of 5-HTT and an antagonist of 5-HT₃ receptor, was the only product exclusively targeting both the 5-HTT and 5-HT₃ receptor, underscoring its unique mechanism of action.

INDUSTRY OVERVIEW

Competitive Landscape of Innovative Small Molecule Antidepressants under Phase II or Later Stage Clinical Development in China

Candidate	Target	Company	Clinical phase	First posted date	Indication
Ammoxetine	NET, 5-HTT	CSPC Pharmaceutical	III	2025/01/14	Depressive disorder
JH201501	DAT, NET, 5-HTT	Jebel Pharmaceutical	III	2024/04/09	Depressive disorder
Aticaprant	κ opioid receptor	Janssen Research & Development	III	2023/10/12	Depressive disorder
Mitizodone Phosphate	5-HT receptor, 5-HT _{1A} receptor	Sunshine Lake Pharma	II/III	2021/07/12	Depressive disorder
LV232	5-HTT, 5-HT₃ receptor	The Company	II	2025/01/16	Depressive disorder
ZG-001	BDNF-TrkB	Zhigen Pharmaceutical	II	2025/01/14	Adult depressive disorder with suicidal intention
NH102	5-HT _{2A} receptor, DAT, NET, 5-HTT	Nhwa Pharmaceutical	II	2024/11/01	Depressive disorder
BI1569912	GluN2B, NMDA receptor	Boehringer Ingelheim GmbH	II	2024/07/12	Depressive disorder
MI078	N/A	Minova Pharmaceutical	II	2024/07/01	Perinatal depression
SAL0114	NMDA receptor	Salubris Pharmaceutical	I/II	2024/01/15	Depressive disorder
JS1-1-01	DAT, NET, 5-HTT	Tasly Pharmaceutical	II	2023/12/04	Depressive disorder
HS-10353	GABAA receptor	Hansoh Pharmaceutical	II	2023/07/03	Perinatal depression
			II	2023/07/05	Depressive disorder
Liafensine	DAT, NET, 5-HTT	Denovo Biopharmaceutical	II	2022/07/29	Refractory depressive disorder
GW117	5-HT _{2C} receptor, MT ₁ /MT ₂ receptor	Guangwei Pharmaceutical	II	2022/05/27	Depressive disorder

Source: CDE, China Insights Consultancy

Antiepileptic Drugs

Epilepsy is a chronic neurological disorder characterized by recurrent seizures, affecting millions of people globally. In 2023, approximately 64.4 million people worldwide are living with epilepsy, and this number is expected to rise to 71.7 million by 2035. In China, approximately 10.3 million people are affected by epilepsy in 2023, with projections indicating an increase to 12.6 million in 2035. Epilepsy is often caused by an imbalance between excitatory and inhibitory states in the nervous system. During an epileptic seizure, individuals may experience involuntary convulsions in a specific part of the body or throughout the entire body (focal or generalized seizures), often accompanied by loss of consciousness and urinary or fecal incontinence. Epileptic seizures are transient clinical events caused by abnormal, excessive, and synchronized neuronal discharges in the brain. Epilepsy significantly impacts patients' daily lives, extending beyond the seizures themselves. Many individuals with epilepsy face barriers in education, employment, and social interactions due to their condition. These challenges are often compounded by coexisting mental health disorders such as anxiety and depression, which further complicate treatment and reduce quality of life.

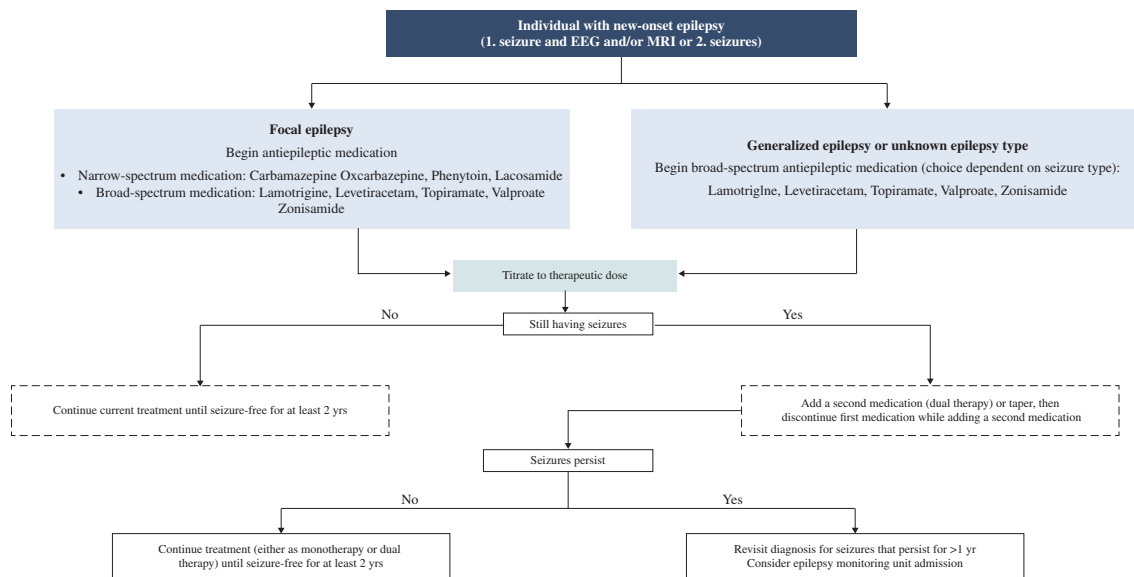
INDUSTRY OVERVIEW

Treatment Paradigm

The treatment pathway for epilepsy begins with the diagnosis of new-onset epilepsy, which is confirmed through seizure history and diagnostic tests. For focal epilepsy, treatment typically starts with narrow-spectrum antiepileptic medication. For generalized epilepsy or cases with an unknown type, broad-spectrum antiepileptic medications are initiated based on the specific seizure type. After a patient receives the treatment, if seizures persist, the next step is to add a second medication (dual therapy) while tapering off the first. If seizures still continue, the diagnosis is revisited, especially if seizures persist for more than a year, and admission to an epilepsy monitoring unit may be considered. If seizures are controlled, treatment is maintained (either monotherapy or dual therapy) until the patient remains seizure-free for at least two years.

The treatment of epilepsy depends on the type of seizure and involves various first-line, add-on, and other reference treatments. Among all epilepsy patients, approximately 40% are non-convulsive (primarily manifesting as absence seizures), while the rest exhibit convulsive symptoms. Of patients with convulsive symptoms, approximately one-third have generalized seizures, and two-thirds have focal seizures. For generalized seizures, first-line treatments include valproate, lamotrigine, carbamazepine, oxcarbazepine, and levetiracetam. For focal seizures, first-line treatments include carbamazepine, lamotrigine, oxcarbazepine, levetiracetam, and valproate.

Medication Treatment Paradigm of Epilepsy in China



Source: *New-Onset Seizure in Adults and Adolescents, Clinical Diagnosis and Treatment Guidelines Epilepsy Subsection (2023 Revised Edition)* (临床診療指南癲癇病分冊(2023修訂版)), China Insights Consultancy

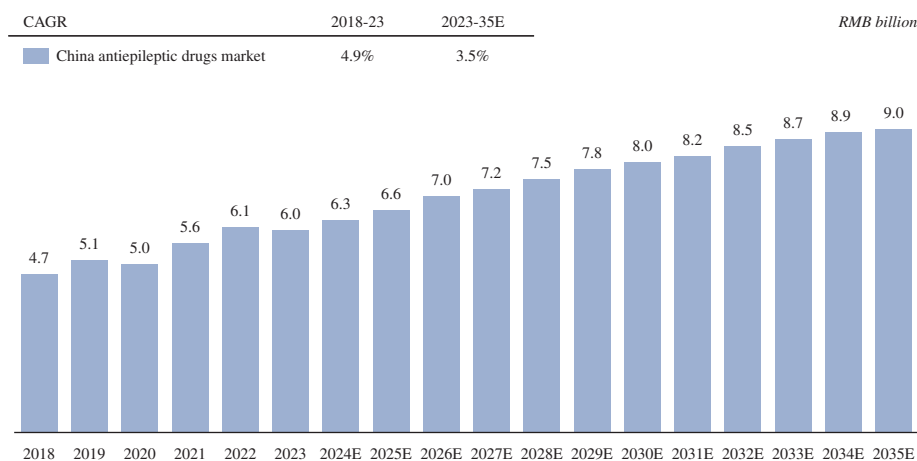
INDUSTRY OVERVIEW

Current epilepsy medications face persistent challenges, including limited efficacy and significant side effects. Antiepileptic drugs, such as phenobarbital, phenytoin, carbamazepine, and clonazepam, are associated with notable side effects such as drowsiness, dizziness, and nausea, and require strict dosage control due to numerous drug interactions. Other antiepileptic drugs, including gabapentin, lamotrigine, levetiracetam, and pregabalin, offer fewer side effects but have not substantially improved the overall efficacy or tolerability of treatment. Additionally, although 70% of epilepsy patients achieve seizure control with antiepileptic drugs, approximately 30% suffer from refractory epilepsy, where seizures remain uncontrolled despite treatment. These challenges highlight a significant unmet clinical need for the development of safer and more effective innovative therapies.

Market Size

The antiepileptic drug market is projected to experience steady growth in the coming years. In China, the market was valued at RMB4.7 billion in 2018, rising to RMB6.0 billion in 2023, reflecting a CAGR of 4.9% over the five-year period. It is anticipated to grow to RMB9.0 billion in 2035, at a CAGR of 3.5% from 2023 to 2035.

Historical and Forecasted Market Size of Antiepileptic Drugs in China, 2018-2035E



Sources: *Clinical Diagnosis and Treatment Guidelines for Epilepsy (2023 Revised Edition)*, China Insights Consultancy

Competitive Landscape

As of the Latest Practicable Date, there were 23 innovative antiepileptic small molecules approved for marketing in China. Additionally, there were six innovative small molecule antiepileptic drugs under development in China.

INDUSTRY OVERVIEW

Competitive Landscape of Innovative Small Molecule Antiepileptic Drugs under Clinical Development in China

Candidate	Company	Clinical phase	First posted date	Indication
TAK-935	Takeda Pharmaceutical	III	2022/05/16	Treatment of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome in patients 2 years of age and older
派恩加濱片 (Pynegabine)	Hainan Haiyao	II	2024/04/23	Focal epilepsy in patients who are refractory to or intolerant of other antiepileptic medications
TPN102	The Company	I	2020/03/17	Epilepsy
WX0005	Harbin Pharmaceutical Group	I	2020/05/25	Intended for the treatment of epilepsy
Phenzolzine capsule	Jilin Yinglian Shangde	I	2021/04/19	Tonic-clonic seizures, absence seizures, and temporal lobe epilepsy
NS-041	Neushen Therapeutics	I	2024/11/29	Epilepsy

Note: TAK-935 failed to achieve two of the primary endpoints in a Phase III clinical trial.

Sources: CDE, China Insights Consultancy

Antipsychotic Drugs

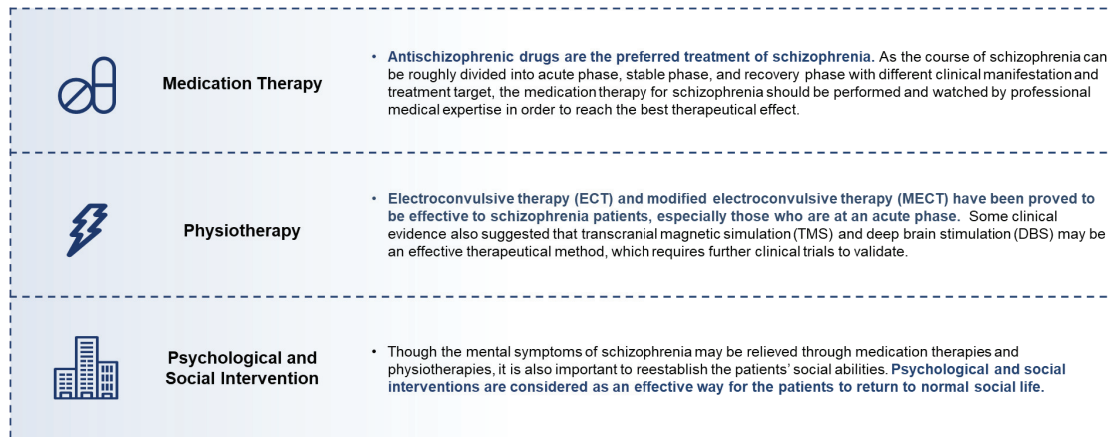
Schizophrenia is a severe mental disorder characterized by disturbances in perception, emotion, cognition, and behavior, typically emerging in young adulthood and often resulting in lifelong suffering. In 2023, schizophrenia affected 24.6 million people globally, with the number expected to reach 30.3 million in 2035. In China, the condition affected 15.2 million people in 2023, with projections indicating 18.0 million in 2035. The disorder presents with positive symptoms such as hallucinations, delusions, and thought disturbances, as well as negative symptoms including social withdrawal, emotional blunting, and lack of motivation. While the precise causes remain unclear, schizophrenia is believed to arise from a combination of genetic, neurodevelopmental, neurobiochemical, and social psychological factors.

Treatment Paradigm

Antipsychotic drugs are the preferred treatment for schizophrenia. They can be generally divided into conventional and atypical drugs. Conventional antipsychotic drugs primarily target D₂ receptor, while atypical antipsychotic drugs target multiple receptors, including those for dopamine and 5-HT, to offer a broader range of targets and improved efficacy in modulating neurotransmitter balances. Atypical antipsychotic drugs are now considered first-line treatments due to their better efficacy and safety profiles. In addition to medication, electroconvulsive therapy and modified electroconvulsive therapy are also recommended treatments, particularly during the acute phase. Psychological and social interventions are also recommended to help patients reintegrate into society and regain social skills.

INDUSTRY OVERVIEW

Treatment Paradigm of Schizophrenia in China



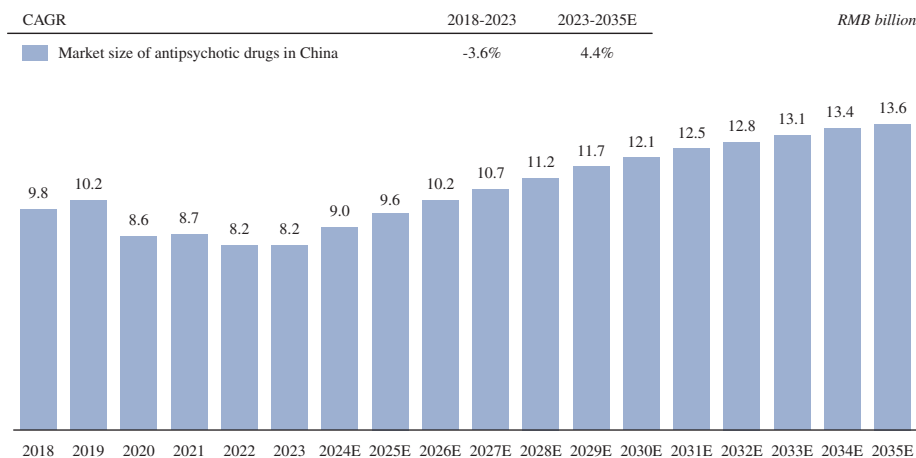
Sources: Psychiatry, China Insights Consultancy

Current treatments for schizophrenia primarily rely on antipsychotic medications, which effectively alleviate positive symptoms such as hallucinations and delusions but have limited impact on negative symptoms, including social withdrawal, emotional blunting, and cognitive impairments. Moreover, long-term use of these medications carries risks of severe side effects, such as metabolic disturbances and movement disorders, resulting in poor patient adherence and an increased risk of relapse. Consequently, there is an urgent need for safer and more effective therapies that comprehensively address multiple dimensions of the disorder.

Market Size

The antipsychotic drug market is projected to experience steady growth in the coming years. In China, the market was valued at RMB8.2 billion in 2023 and is anticipated to grow to RMB13.6 billion in 2035, at a CAGR of 4.4% from 2023 to 2035.

Historical and Forecasted Market Size of Antipsychotic Drugs in China, 2018-2035E



Note: During 2020-2023, the allocation of medical resources was impacted, particularly for the treatment of non-acute conditions. Additionally, while public awareness of mental health issues increased, market growth was hindered by disruptions in supply chains and challenges in accessing medical services during this period.

Sources: Lancet psychiatry, China Insights Consultancy

INDUSTRY OVERVIEW

Competitive Landscape

As of the Latest Practicable Date, 22 innovative antipsychotic small molecules had been approved for marketing in China. Additionally, there were 16 innovative small molecule antipsychotic drugs under clinical development in China.

Competitive Landscape of Innovative Small Molecule Antipsychotic Drugs under Clinical Development in China

Candidate	Target	Company	Clinical phase	First posted date	Indication
BI 425809	GlyT1	Boehringer Ingelheim International	III	2021/04/01	Schizophrenia
KarXT	M ₁ /M ₄ receptor, mACh receptor	Zai Lab/Karuna Therapeutics	III	2023/04/23	Schizophrenia
SIP16398	5-HT _{1A} receptor, 5-HT _{2A} receptor, D ₂ receptor	Zhongze Therapeutics	II	2023/10/27	Schizophrenia
HS-10380	5-HT _{1A} receptor, D ₂ receptor, D ₃ receptor	Hansoh Pharmaceutical	II Ib/II	2024/04/19 2023/06/19	Schizophrenia at acute phase Schizophrenia
NHL35700	PDE10A	Nhwa Pharmaceutical	II	2024/04/02	Schizophrenia
JX11502MA	5-HT _{1A} receptor, 5-HT _{2A} receptor, D ₂ receptor	Jingxin Pharmaceutical	II	2024/05/13	Adult schizophrenia
CY150112	DRD3	Nhwa Pharmaceutical	Ib	2022/01/18	Schizophrenia
Pomaglumedad methionil	mGluR2 and mGluR3	Denovo Biopharma	I	2019/10/18	Schizophrenia
MK-8189	PDE10A	MSD International	I	2021/10/19	Schizophrenia
TPN672	5-HT _{1A} receptor, 5-HT _{2A} receptor, D ₂ /D ₃ receptor	Kanion Pharmaceutical	I	2022/07/11	Schizophrenia
VV119	D₂ receptor, D₃ receptor, 5-HT_{1A} receptor, 5-HT_{2A} receptor, 5-HTT	The Company	I	2023/10/18	Schizophrenia
NH300231	5-HT _{2A} receptor, DRDs	Nhwa Pharmaceutical	I	2024/01/02	Schizophrenia
HS-10509	N/A	Hansoh Pharmaceutical	I	2024/02/27	Schizophrenia
LPM526000133	N/A	Luye Pharma Group	I	2024/05/06	Schizophrenia with negative symptoms
LPM787000048	5-HT _{2C} receptor and TAAR1	Luye Pharma Group	I	2024/08/13	Schizophrenia
NS-136	M ₄ receptor	Neushen Therapeutics	I	2024/11/12	Schizophrenia

Sources: CDE, China Insights Consultancy

INDUSTRY OVERVIEW

Reproductive Health Drugs

Reproductive health conditions affect both male and female reproductive systems, with a wide range of disorders. In women, common conditions include polycystic ovary syndrome, endometriosis, infertility, cervicitis, and sexually transmitted infections. For men, reproductive health issues primarily involve andrology-related disorders such as ED, PE, BPH, oligospermia, and azoospermia. ED, in particular, can lead to psychological distress, diminished self-esteem, and relationship challenges, while also potentially indicating underlying cardiovascular or metabolic issues. PE significantly impacts sexual satisfaction and overall quality of life. Chronic urinary symptoms associated with BPH can disrupt daily activities and sleep, progressively increasing the risk of urinary retention and further reducing quality of life.

The market size of reproductive disease drug global market was US\$78.2 billion in 2023 and is projected to remain relatively stable, with a slight increase to US\$78.4 billion in 2035. The reproductive drug market in China has shown significant growth, driven by increased awareness of reproductive health, rising drug penetration, and higher household income levels. With economic development and improved patient affordability, more people can access and afford reproductive health medications. As such, in China, the reproductive disease drug market was valued at RMB34.2 billion in 2023, and is projected to reach RMB39.8 billion in 2035.

PDE5 Inhibitors

PDE5 inhibitors work by inhibiting phosphodiesterase type 5, increasing cyclic guanosine monophosphate levels in cavernoma smooth muscle, enhancing nitric oxide-mediated vasodilation, thereby improving erectile function. They are the first-line medication for ED treatment with a Grade A recommendation.

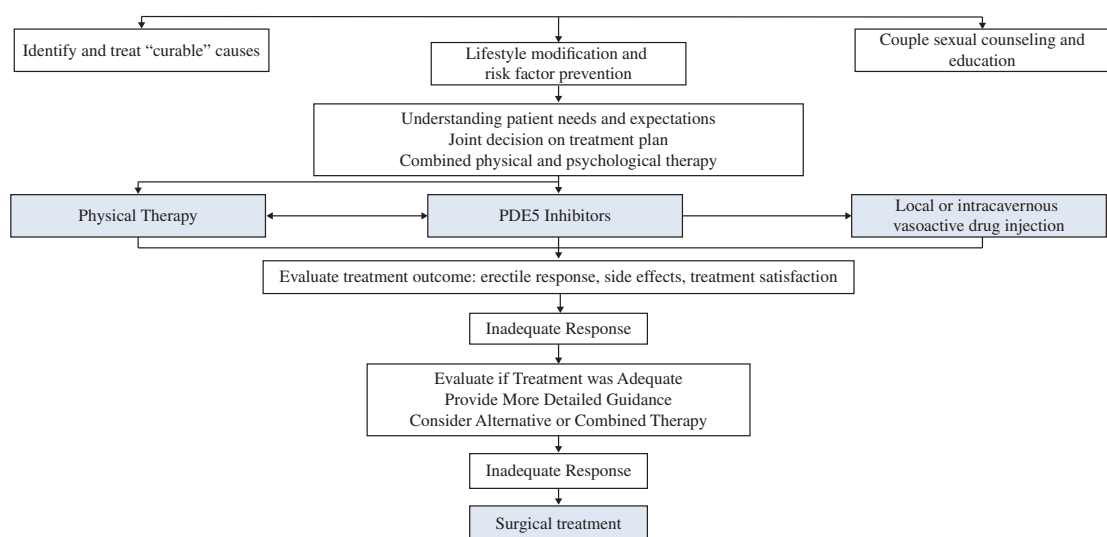
The global market size of PDE5 inhibitors was US\$10.0 billion in 2023 and is projected to remain relatively stable, with a slight increase to US\$10.1 billion in 2035. In China, the PDE5 inhibitor market was valued at RMB9.3 billion in 2023. With the expanded medical insurance coverage, improved healthcare channels, and rising disposable income, the market size of PDE5 inhibitor is projected to reach RMB15.2 billion in 2035.

Treatment Paradigm for ED

The treatment of ED involves a comprehensive approach, starting with identifying and treating any curable underlying causes, such as diabetes or hypertension. Lifestyle modifications, including improved diet, increased physical activity, and reduced alcohol or smoking, are recommended to address risk factors. Couple sexual counseling and education are provided to address emotional and relational aspects, while treatment plans are tailored to the patients’ needs, preferences, and expectations through shared decision-making. A combined approach of physical therapies, such as PDE5 inhibitors and vasoactive drug injections, alongside psychological support is often utilized. If treatment response is inadequate, further evaluation is necessary, with consideration for alternative therapies or combined treatments. In some cases, surgical options may be explored.

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Treatment Paradigm for ED in China



Sources: *The Chinese Society of Andrology's Guidelines for the Diagnosis and Treatment of ED, China Insights Consultancy*

PDE5 inhibitors remain to be the first-line treatment of ED and are the most commonly prescribed medication for this condition. However, many of the marketed PDE5 inhibitors, including sildenafil, tadalafil, and vardenafil, exhibit high inhibitory activity on PDE6 and PDE11, leading to significant adverse effects in patients. Recorded side effects include back pain, muscle pain, headache, upper abdominal discomfort, nasal congestion, flushing, vision blurred, dizziness and palpitation. Due to the safety concerns, special considerations are included in the drug specifications to warn their use in patients with renal or hepatic impairment. However, as a lifestyle medication, a compound used to treat ED is expected to meet heightened safety requirements. This highlights a significant opportunity for the development of new PDE5 inhibitors with improved safety profiles to better meet patient needs.

Competitive Landscape for ED Treatment

As of the Latest Practicable Date, the FDA approved four PDE5 inhibitors for the treatment of ED: sildenafil from Pfizer, vardenafil from Bayer, tadalafil from Eli Lilly, and avanafil from Metuchen. In China, the NMPA approved these four PDE5 inhibitors as well as aildenafil from Youcare Pharmaceutical Group for ED treatment. Sildenafil and tadalafil dominate the market, holding the majority of market share both in China and globally in 2023.

As of the Latest Practicable Date, there were seven PDE5 inhibitors under development for ED treatment in China. TPN171 stood out as one of the two product candidates that submitted NDA applications.

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Competitive Landscape of PDE5 Inhibitor for ED Treatment under Clinical Development in China

Candidate	MoA	Company	Clinical phase	First posted date	Indication	Single/ Combo
TPN171	PDE5i	the Company	NDA	2024/03/01	ED	Single
Youkenafil Hydrochloride	PDE5i	Yangtze River Pharmaceutical	NDA	2024/01/30	ED	Single
TPN729MA	PDE5i	Topfond Pharmaceutical	III	2022/10/09	ED	Single
Fadanafil	PDE5i	Xuanzhu Bio	II	2021/08/10	ED	Single
DDCI-01	PDE5i	Chongqing Dikangerle Pharmaceutical	II	2023/11/21	LUTS secondary to BPH with ED	Single
cms203	PDE5i	Shandong Lukang Pharmaceutical	II	2023/12/25	ED	Single
Xiongdenafil Citrate	PDE5i	Suzhou Maidixian Pharmaceutical	I	2019/07/30	ED	Single

Sources: CDE, China Insights Consultancy

CHINA GENERIC DRUG INDUSTRY

To enhance competition and increase drug accessibility, generic drugs are introduced to the market. In order to obtain marketing approval, generic drugs must demonstrate they are as safe and effective as the brand-name drug, achieving both pharmaceutical equivalence and clinical equivalence. Pharmaceutical equivalence means that the active ingredients, dosage form, strength, route of administration, and labeling of the generic drug must match those of the brand-name drug. For oral formulations, clinical equivalence is typically demonstrated through bioavailability studies. This requires that the rate and extent of drug absorption in the body (as measured by C_{max} and AUC) for the generic fall strictly within the range of 80% to 125% of the brand-name drug.

The size of the generic drug market in China decreased from RMB703.9 billion in 2018 to RMB654.3 billion in 2023, due to disruptions in supply chains and challenges in accessing medical services. It is expected to grow at a CAGR of 0.9% from 2023 to 2035, reaching RMB724.6 billion by 2035.

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Growth Drivers and Future Trends

To foster competition in the pharmaceutical sector, the Chinese government has introduced several policies designed to promote the development of high-quality generic drugs. One such policy grants a market exclusivity period to the first chemical generic drug that successfully challenges a patent and is approved for marketing. During this period, the drug regulatory authority will not approve any other generic versions of the same drug for 12 months, except in cases of joint patent challenges. This exclusivity is limited to the original patent term of the challenged drug. Furthermore, China’s centralized volume-based procurement (“**VBP**”) initiative aims to reduce drug prices by purchasing drugs that have passed consistency evaluations in bulk, which helps lower patient costs and drive industry development. For companies selected in the VBP process, drug sales volumes are guaranteed by national and provincial governments, enabling cost reductions through economies of scale. This not only minimizes marketing and sales expenses but also allows generic drug manufacturers to manage costs and preserve profit margins.

Dapoxetine Hydrochloride

Dapoxetine hydrochloride is indicated for the treatment of PE symptoms in men aged 18 to 64 years. PE is a common form of male sexual dysfunction, characterized by a short intravaginal ejaculatory latency time, lack of control over ejaculation, sexual satisfaction issues, and relationship difficulties with a partner. In China, the PE market was valued at RMB1,523.6 million in 2023 and is projected to reach RMB3,536.8 million by 2035, growing at a CAGR of 7.3%.

PE treatment typically involves three main approaches: pharmacological therapy, behavioral therapy, and sexological psychological interventions. Given the complex etiology and symptomatology of PE, pharmacological therapy is often combined with psychological and behavioral interventions for more effective management. For patients with PE, addressing other conditions such as ED, sexual dysfunctions, or urogenital infections (e.g., prostatitis) is also recommended. Dapoxetine hydrochloride and local anesthetics are considered first-line treatment options for PE.

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Our major competitors include both national and regional manufacturers of dapoxetine hydrochloride, as well as an international pharmaceutical company. The table below provides a description of their business scopes and respective market shares:

Ranking	Company	Headquarter	Market Share	Scope of Business	Product Description
1	Group A	Shandong, China	30.0%	the research and development, production and sales of anti-tumor drugs, cardiovascular and cerebrovascular drugs, diabetes drugs, dermatology drugs, gynecological disease drugs, and biological drugs	Tablet, 30mg
2	Group B	Berlin, Germany	17.0%	the production and sale of high-quality pharmaceutical products, mainly in the fields of gastroenterology, pain management, cardiovascular diseases, biologics and oncology	Tablets, 30mg, brand name drug
3	Group C	Sichuan, China	15.0%	the research and development, production and sales of products, mainly in anesthesia and analgesia, central nervous system, anti-infection, parenteral nutrition and other fields	Tablets, 60mg
4	Group D	Jiangsu, China	14.0%	the production and sale of tablets, hard capsules, granules, suppositories, and APIs, mainly in the fields of urinary system, antihistamines, cardiovascular, steroid hormones and antibiotics	Tablets, 30mg
5	Group E	Henan, China	6.7%	the production, sales and pharmaceutical operation of finished preparations, chemical synthesis APIs and biological fermentation APIs, mainly in antibiotics, cardiovascular and cerebrovascular diseases, diabetes and other fields	Tablets, 30mg
Others			17.3%		
Total			100%		

Sources: China Insights Consultancy

Rebamipide

Rebamipide is a medication commonly prescribed to treat gastrointestinal disorders such as PUD, gastritis, and *Helicobacter pylori* infection. It has been shown to increase gastric mucosal prostaglandins, inhibit the production of the superoxide anion radical, scavenge the hydroxyl radical, suppress the production of inflammatory cytokines, and reduce gastric mucosal inflammatory cell infiltration. The market size for rebamipide was valued at RMB901.8 million in 2023, with projections indicating growth to RMB1,505.5 million by 2035, reflecting a CAGR of 4.4%.

PUD is a disease defined by a localized defect in the gastric or duodenal mucosa, typically due to an imbalance between protective factors and aggressive elements such as gastric acid and pepsin, often linked to *Helicobacter pylori* infection or NSAID use. Gastritis, characterized by inflammation of the gastric mucosa, can be acute or chronic, with chronic gastritis most commonly caused by *Helicobacter pylori* infection.

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The treatment goals for PUD include eliminating the underlying cause, such as eradicating *Helicobacter pylori* or discontinuing NSAIDs, relieving symptoms, promoting ulcer healing, preventing recurrence, and avoiding complications. For chronic gastritis, the focus is on addressing the root cause, alleviating symptoms, improving the health of the gastric mucosa, enhancing the patient’s quality of life, and preventing relapses or complications. The primary treatment for both conditions involves pharmacotherapy, supplemented by dietary and lifestyle modifications.

Our major competitors include both national and regional manufacturers of rebamipide, as well as an international pharmaceutical company. The table below provides a description of their business scopes and respective market shares:

Ranking	Company	Headquarter	Market Share	Scope of Business	Product Description
1	Group F	Zhejiang, China	54.5%	the R&D, production and sale of drugs in digestion field	Tablets, 0.1g
2	Group G	Tokyo, Japan	35.5%	the R&D, production and sale of nutraceuticals (nutrition and pharmaceuticals) and cosmetics (cosmetics and medicine)	Tablets, 0.1g, brand name drug
3	Group H	Chongqing, China	10.0%	the R&D, production and sale of APIs and pharmaceutical preparations, mainly in cardiovascular, nervous system, anti-infection and other categories	Tablets, 0.1g
Others					
Total			100%		

Sources: China Insights Consultancy

REPORT COMMISSIONED BY CHINA INSIGHTS CONSULTANCY

In connection with the [REDACTED], we have engaged China Insights Consultancy Limited to conduct a detailed analysis and prepare an industry report on the small molecule drug market in China and globally. China Insights Consultancy Limited is an independent global market research and consulting company which was founded in 2014 and is based in Shanghai. Services provided by China Insights Consultancy Limited include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The contract sum to China Insights Consultancy Limited is RMB500,000 for the preparation of the CIC Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the results of the CIC Report. Except for the CIC Report, we did not commission any other industry report in connection with the [REDACTED]. We have included certain information from the CIC Report in this document because we believe such information facilitates an understanding of the small molecule drug market for potential [REDACTED]. China Insights Consultancy Limited prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, China Insights Consultancy Limited contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. China Insights Consultancy Limited believes that the basic

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assumptions used in preparing the CIC Report, including those used to make future projections, are factual, correct and not misleading. China Insights Consultancy Limited has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. China Insights Consultancy Limited research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

The market projections in the commissioned report are based on the following key assumptions: (i) the overall social, economic and political environment in the global economy is expected to remain stable during the forecast period; (ii) relevant key drivers are likely to maintain a steady growth trend over the next decade; (iii) increasing number of drug penetration, increasing amount of R&D expenditures, increasing patient affordability, etc.

Our Directors, after taking reasonable care, confirm that to the best of their knowledge, there is no material adverse change in the market information since the date of the relevant data contained in the CIC Report and up to the Latest Practicable Date which may qualify, contradict or have an impact on the information in this section.

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OVERVIEW OF LAWS AND REGULATIONS IN CHINA

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the major PRC regulatory authorities and PRC laws and regulations that we believe are relevant to our business and operations in the PRC.

PRINCIPAL REGULATORY AUTHORITIES

NMPA and Center for Drug Evaluation

National Medical Products Administration (國家藥品監督管理局) (formerly known as the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”)) (the “NMPA”) is the department in charge of the pharmaceutical industry of China. It is primarily responsible for supervision and management of safety of pharmaceuticals, medical devices and cosmetics, including drawing up the relevant laws and regulations; conducting standard management, registration management, quality management and post-market risk management for drugs, medical devices and cosmetics; and organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics and etc.

Center for Drug Evaluation, NMPA (國家藥品監督管理局藥品審評中心) (the “CDE”) is the technical evaluation unit for drug registration with NMPA. It is primarily responsible for conducting technical evaluation on the drugs application for registration and verifying the relevant drug registrations.

NHC

The National Health Commission (國家衛生健康委員會) (formerly known as the National Health and Family Planning Commission (國家衛生和計劃生育委員會)) (the “NHC”), is primary national regulator for national public health and medical system.

It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

NHSA

The National Healthcare Security Administration (國家醫療保障局) (the “NHSA”), a new authority established in May 2018, is directly under the State Council and responsible for the management of the healthcare security system.

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It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; organizing the formulation of a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

PRINCIPAL REGULATORY PROVISIONS

Laws and Regulations on New Drugs

Research and development of new drugs

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “Drug Administration Law”) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “Implementation Regulations”) promulgated by the State Council in August 2002 and last amended on March 2, 2019, have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and the Implementation Regulations, the PRC encourages the research and development of new drugs, and protects the legal rights and interests in the research and development of new drugs. The developer and clinical trial applicant of any new drug shall truthfully submit the new drug’s manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

Non-clinical research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Administrative Measures for Good Laboratories Practice (《藥物非臨床研究質量管理規範》), which was promulgated in August 2003 and amended in July 2017 by the CFDA. In April 2007, the CFDA issued the Circular on Measures for Certification of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

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Animal Testing

According to the Regulations for the Regulation on Administration of Experimental Animals (《實驗動物管理條例》) issued by the State Scientific and Technological Commission on November 14, 1988 and last amended by the State Council on March 1, 2017, the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly issued by the State Scientific and Technological Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997 and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) issued by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and effective from January 1, 2002, using, breeding, providing, transporting experimental animals shall be subject to some rules and requirements, and performing experimentation on animals requires a Certificate for Use of Experimental Animals.

Application for clinical trial

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the CDE from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “Circular 27”), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with Circular 27 and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

After obtaining the approval of clinical trial from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of clinical trial to obtain an exclusive trial registration number, and then complete the subsequent information registration before the first patient is enrolled in the trial and submit the registration for public disclosure for the first time.

Conduct of clinical trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial

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Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such clinical trial institutions shall be subject to filing requirements, with the exception of institutions that only engage in analysis of biological samples which shall not be subject to such filing requirements. The NMPA is responsible for setting up a filing management information platform for the registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information from the supervision and inspection activities conducted by the drug regulatory authorities and competent healthcare authorities.

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including pre-clinical trial preparation, trial protocols, protection of testees’ rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

New drug registration

Pursuant to Circular 27, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization for a new drug before the drug can be sold in the China market. According to Circular 27, the holders of any of the following drugs can apply for conditional approval of such drugs: (1) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective

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treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (2) drugs which are urgently needed for public health and data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, the benefits of both of which are assessed to be outweigh the risk.

Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law, China implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

The marketing authorization holders may manufacture drugs by themselves or entrust a pharmaceutical manufacturing enterprise to manufacture drugs. Likewise, they may sell drugs by themselves or entrust a pharmaceutical distribution enterprise to sell drugs. However, marketing authorization holders may not entrust a pharmaceutical manufacturing enterprise to produce blood products, narcotic drugs, psychotropic drugs, medical-use toxic drugs or pharmaceutical precursor chemicals, except as otherwise stipulated by the drug regulatory department under the State Council.

The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities.

Where the marketing authorization holder is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the marketing authorization holder and jointly assume responsibilities of the marketing authorization holder with the overseas enterprise.

Registration of Generic Drugs

According to the Circular 27, a generic drug shall be consistent with the quality and efficacy of the reference preparation. The applicants may directly file an application for drug marketing authorization if the applicants, after assessing, believe it is unnecessary or impossible for the generic drugs to go through clinical trials and the relevant generic drugs meet the conditions for exempting a clinical trial. According to the Circular on Implementation of Filing Management of Bioequivalence Trials of Chemical Drug (《關於化學藥生物等效性試驗實行備案管理的公告》), the management of bioequivalence trials of chemical drug has been changed from examination and approval to filing management.

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Pursuant to the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the General Office of the State Council (《國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見》) promulgated on February 6, 2016 and the Opinions of Relevant Matters Concerning Implementing the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the NMPA (《關於落實〈國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見〉有關事項的意見》), promulgated on May 25, 2016, generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, including domestic generic drugs, imported generic drugs and the indigenous varieties of the innovative drugs, shall carry out consistency evaluation. In principle, the consistency evaluation should be completed before the end of 2018 for the generic oral solid preparations approved for sale before October 1, 2007 and listed in the National Essential Drug List (2012 version) (《國家基本藥物目錄(2012年版)》). For any other generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, after the first drug produced by a pharmaceutical enterprise passes the consistency evaluation, other pharmaceutical enterprises shall complete the consistency evaluation for their identical drugs within three years in principle; no registration will be granted in case of failure to do so as required within the prescribed time limit.

Pursuant to the Circular on Relevant Matters Concerning Consistency Evaluation for Quality and Curative Effect of Generic Drugs (《關於仿製藥質量和療效一致性評價有關事項的公告》) further promulgated by NMPA on December 28, 2018, the time limit for consistency evaluation of the drugs included in the National Essential Drug List (2018 version) (《國家基本藥物目錄(2018年版)》) will no longer be set uniformly. For generic drugs, including essential drug varieties, approved for marketing before the implementation of new registration classification of chemical drugs, after the first drug has passed the consistency evaluation, other drug manufacturers should complete the consistency evaluation for their identical drugs within three years in principle. If it is not completed within the time limit, the enterprise may apply to the local provincial drug regulatory authority for an extension of the evaluation if the drug is deemed to be clinically necessary and in short supply in the market. If the registration is not completed within the extended time limit, it shall not be re-registered.

Laws and Regulations on Gathering, Collection and Filing of Human Genetic Resources

In June 1998, the Ministry of Science and Technology (the “MOST”) and the Ministry of Health (the “MOH”, which was canceled in the institutional reform of the State Council in 2013, its functions were first inherited by the National Health and Family Planning Commission and then by the NHC, which was established in 2018) promulgated the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》), which sets out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the MOST in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人

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類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the MOST in August 2015, the gathering and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be filed for record with the China Human Genetic Resources Management Office through an online system. The MOST promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the marketing of drugs in China.

Pursuant to the Regulations on the Management of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), last amended by the State Council on March 10, 2024 and came into effect on May 1, 2024, the State supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations. The Implementing Rules of the Regulation on the Administration of Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which was promulgated by the MOST on May 26, 2023 and became effective on July 1, 2023, further provides specific requirements on the collection, preservation, utilization and external provision of China’s human genetic resources.

The Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “Biosecurity Law”), which was promulgated by SCNPC on October 17, 2020 and last amended on April 26, 2024, establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants, research, development, and application of biology technology, biosecurity management of pathogenic microbial laboratories, security management of human genetic resources and biological resources, countermeasures for microbial resistance, and prevention of bioterrorism and defending threats of biological weapons. According to the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of the PRC in accordance with the law, upon obtaining the approval or record-filing. The following activities are subject to approval of the competent health department: (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent health department under the State Council, (ii) preserving China’s human genetic resources, (iii) using China’s human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying China’s human genetic resource materials out of the country.

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Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing Certificate

Pursuant to the Drug Administration Law and the Implementing Regulations, a drug manufacturer must obtain a Drug Manufacturing Certificate (藥品生產許可證) from the drug regulatory authority at provincial, autonomous regional or municipal level before it may start manufacturing drugs in the PRC. The Drug Manufacturing Certificate shall indicate the validity period and the scope of production. Each Drug Manufacturing Certificate is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date.

Good Manufacturing Practice

Prior to December 1, 2019, pursuant to the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA in August 2011, when establishing a pharmaceutical manufacturer or a new factory or expanding the production scope, the drug manufacturer is required to submit an application for a good manufacturing practice certification (the “GMP certification”) with the drug regulatory authority. If the Good Manufacturing Practices (the “GMP”) are satisfied, a GMP certificate will be issued. Pursuant to the Circular on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, since December 1, 2019, the GMP and Good Supply Practice (the “GSP”) certifications have been canceled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The drug manufacturer must conduct the manufacturing process in accordance with the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) issued by the Ministry of Health in January 2011, which sets forth a set of detailed standard guidelines governing the manufacture of drugs including institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and adverse event reports.

The Administrative Measures for the Inspection of Pharmaceuticals (Trial) (《藥品檢查管理辦法(試行)》) was promulgated by the NMPA on May 24, 2021 and amended on July 19, 2023, and the Certification Measures for Good Manufacturing Practice for Drugs was repealed simultaneously. The Administrative Measures for the Inspection of Pharmaceuticals (Trial) stipulated that if a drug manufacturer applies for a drug manufacturing license for the first time, it will be subject to on-site inspection under relevant contents of the GMP. If a drug manufacturer applies for re-issuance of drug manufacturing license, relevant authorities shall conduct examination pursuant to risk management principle, taking into account the enterprise’s compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection, if necessary.

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Contract manufacturing of drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) (the “Contract Manufacturing Regulations”) issued by the CFDA in August 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, can such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. Such contract manufacturing arrangements shall be approved by the provincial branch of the NMPA.

The Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) (the “Revised Administrative Measures of Drug Manufacturing”) promulgated by the State Administration for Market Regulation on January 22, 2020 and effective on July 1, 2020 further implements the drug marketing authorization holder system as stipulated in the Drug Administration Law. Drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing Certificate.

Laws and Regulations on Drug Supply

Drug Purchases by Hospitals

According to the Opinion on the Guidance of the Reform of Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and took into effect on February 16, 2000 and the Opinion on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and became effective from September 1, 2000, a medical institution must be defined as a profit-making or non-profit-making institution at the time when it is established. A non-profit-making medical institution is established to provide services to the general public, with its revenue used for maintaining and developing such institution, while a profit-making medical institution is established by investors for the purpose of investment return. The PRC government does not establish any profit-making medical institutions, while non-government entities may establish profit-making medical institutions. Any non-profit-making medical institutions must implement a collective tender system in respect of any drug purchases and any profit-making medical institutions need not to implement such a system according to PRC law.

According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases by Medical Institutions (《關於印發醫療機構藥品集中招標採購試點工作若干規定的通知》) promulgated and became effective on July 7, 2000, the Notice on the Further Standardizing of the Centralized Tender with respect to Drug Purchases By Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated and became effective on August 8, 2001 and the Opinions concerning Further Regulating Purchase of Medicines by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機

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構藥品集中採購工作的意見》) promulgated and took into effect on January 17, 2009, any non-profit-making medical institutions established and/or controlled by any government at a county level or above must implement the centralized tender system in respect of purchase of any drugs which are contained in the Medicines List for National Basic Medical Insurance and are generally used for clinical purposes and purchased in relatively large amount.

The Circular on the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》) promulgated and was effective on July 7, 2010, provides stipulations in detail in respect of the catalog for centralized procurement and methods, procedures, evaluators, expert database construction and management of drugs, further regulating the centralized drug procurement and clarifying the code of conduct on the part of purchasing parties. According to the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs, any non-profit-making medical institutions established by the government at the county level or above or state-owned enterprises (including stock-holding enterprises) must participate in the centralized procurement of medical institutions. The centralized procurement management authority at provincial (municipal or district) level is responsible for compiling the catalog of drugs for centralized procurement by medical institutions within its own administrative region, and narcotic drugs and first class psychoactive drugs with respect to which the special administration is carried out by the state are not included in such catalog for centralized procurement; second class psychoactive drugs, radioactive pharmaceuticals, toxic drugs for medical use, crude drugs, traditional Chinese medicinal materials and traditional Chinese medicine decoction pieces may be excluded from such catalog for centralized procurement.

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the classification purchase of drugs. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement platform. The provincial procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals with its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed manufacturers.

Two-invoice System

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, as required at the executive meeting of the State Council dated April 6, 2016 and under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the “two-invoice System” (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public

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Medical Institutions (for Trial Implementation) (《印發<關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)>的通知》) (the “Circular”), which was effective from December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital. According to the Circular, two-invoice system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.

Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) (the “Product Quality Law”), promulgated by the Standing Committee of the NPC on February 22, 1993 and latest amended on December 29, 2018, is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them, and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable for compensating for any bodily injuries or property damages, other than the defective product itself, resulting from the defects in the product, unless the manufacturer is able to prove that (1) the product has never been distributed; (2) the defects causing injuries or damages did not exist at the time when the product was distributed; or (3) the science and technology at the time when the product was distributed was at a level incapable of detecting the defects. A seller shall be liable for compensating for any bodily injuries or property damages of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

On May 28, 2020, the Civil Code of the PRC (《中華人民共和國民法典》) was adopted by the third session of the 13th NPC, which came into effect on January 1, 2021. According to the Civil Code of the PRC, a patient may make a claim against the drug marketing authorization holder, a medical institution or producer for any damage arising from defects of drugs.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers’ rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Where the goods or services provided by a business operator do not satisfy quality requirements, the consumer may require the business operator to perform replacement or repair obligations.

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Drug Advertisement

Pursuant to the Advertisement Law of the PRC (《中華人民共和國廣告法》), which was promulgated by Standing Committee of the NPC on October 27, 1994 and effective from February 1, 1995 and latest amended and effective from April 29, 2021, advertisements shall not contain false statements or be deceitful or misleading to consumers. Advertisements relating to pharmaceuticals and medical devices, shall be reviewed by relevant authorities in accordance with applicable rules before being distributed by broadcasting, movies, television, newspapers, journals or otherwise. The Advertisement Law further stipulates that advertisements for medical treatment, pharmaceutical products or medical devices shall not contain: (i) any assertion or guarantee for efficacy and safety; (ii) any statement on cure rate or effectiveness rate; (iii) any comparison with the efficacy and safety of other pharmaceutical products or medical devices or with other healthcare institutions; (iv) recommendation or endorsement of an advertising endorser; or (v) other items as prohibited by laws and regulations.

Pursuant to the Interim Measures for the Administration of Internet Advertisement (《互聯網廣告管理暫行辦法》) which was promulgated by the State Administration of Industry and Commerce on July 4, 2016 and became effective as of September 1, 2016, the Internet advertisement must be visibly marked as “advertisement”. Advertisements for special commodities or services such as medical treatment, pharmaceuticals, foods for special medical purposes, medical instruments, agrochemicals, veterinary medicines and other health foods must be reviewed by competent authorities before online publication. On February 25, 2023, the SAMR promulgated the Measures for Administration of Internet Advertising (《互聯網廣告管理辦法》) (the “Internet Advertising Measures”), which replaced the Interim Measures for the Administration of Internet Advertisement, and came into effect as of 1 May 2023. Pursuant to the Internet Advertising Measures, Internet advertisers are prohibited from publishing advertisements of prescription drugs on the Internet. Besides, Internet advertisers are prohibited from publishing advertisements for medical treatment, drugs, medical devices, health food and formula food for special medical purposes in disguised form by way of introducing knowledge on health or health maintenance. When introducing knowledge on health or health maintenance, the address, contact information, shopping links and other contents of sellers or service providers of relevant medical treatment, drugs, medical devices, health food, or formula food for special medical purposes shall not be presented on the same page or together with other contents.

Pursuant to the Measures for Administration of Medical Advertisement (《醫療廣告管理辦法》), which were jointly promulgated by the State Administration for Industry and Commerce and the Ministry of Health on November 10, 2006 and effective on January 1, 2007, medical advertisements shall be reviewed by relevant health authorities and obtain a Medical Advertisement Examination Certificate before being released. Medical Advertisement Examination Certificate is valid for one year and maybe renewed upon application.

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Pursuant to the Measures Regarding the Administration of Drug Information Service through the Internet (《互聯網藥品信息服務管理辦法》), which was promulgated by the CFDA and effective from July 8, 2004, and amended and effective from November 17, 2017, the Internet drug information services, referring to that of providing medical information (including medical devices information) services to Internet users through the Internet, are classified into two categories, namely, profit-making services and non-profit services. Any website intending to provide drug information services through Internet shall be approved by NMPA at provincial level before applying for an operation permit or record-filing from the authority in charge of information industry under the State Council or the administration of telecommunication at the provincial level.

Commercial Briberies in Pharmaceutical Industry

According to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) promulgated in January 2007 and amended in December 2013, where a manufacturer of drugs, medical devices and medical disposables, an enterprise, an agency or an individual offers staff of a medical institution any items of value or other benefits, the enterprise should be listed in the adverse records with respect to commercial bribery in the event of the following circumstances: (1) where the act has constituted a crime of bribery as determined by the ruling of a people’s court, or where the circumstance of crime is not serious enough for the imposition of criminal punishment and criminal punishment is exempted as decided by the people’s court in accordance with the Criminal Law; (2) where the circumstance of the crime of bribery is minor and the relevant people’s procuratorate has decided not to lodge a prosecution; (3) where a discipline inspection and supervision authority has initiated a case of bribery and conducted investigation, and punishment has been imposed in accordance with the law; (4) where administrative penalties against the act of bribery have been imposed by, inter alia, the finance administration, the SAMR, the NMPA; (5) any other circumstances specified by laws, regulations and rules. If medical production and operation enterprises are listed into the Adverse Records of Commercial Briberies for the first time, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies in local province for two years since publication of the record, and public medical institution, and medical and health institutions receiving financial subsidies in other province shall lower their rating in bidding or purchasing process. If medical production and operation enterprises are listed into the Adverse Records of Commercial Bribery for twice or more in five years, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

According to the Guiding Opinions on Establishment of the Trustworthiness Evaluation System for Drug Prices and Procurement by Bidding (《關於建立醫藥價格和招採信用評價制度的指導意見》) promulgated by the NHSA in August 2020 and took effect simultaneously, the NHSA would establish a catalogue of dishonest matters involving drug prices and procurement by bidding, and the kickbacks or other improper benefits in the purchase and sale of drugs, tax-related violations of laws, monopolistic practices, improper pricing practices,

REGULATORY OVERVIEW

disruption of the order of centralized procurement, malicious breach of contracts and other malpractices, will be included in such catalogue. Provincial centralized procurement agencies shall assess and rate the dishonest conduct of pharmaceutical enterprises into four levels: general, medium, serious and particularly serious, based on the nature, circumstances, effectiveness and impact of such dishonest conduct. Further, the provincial centralized procurement agencies shall, according to the trustworthiness ratings of pharmaceutical enterprises, take punitive measures, such as warnings and admonishments, restriction on market entry, and release of dishonest information.

Online Pharmaceuticals Sales

On August 3, 2022, the SAMR promulgated the Measures for Supervision and Administration of Online Pharmaceuticals Sales (the “Online Pharmaceuticals Sales Measures”) (《藥品網絡銷售監督管理辦法》), which took effect on December 1, 2022. The Online Pharmaceuticals Sales Measures provides specific and explicit rules for the online sales of prescription drugs, which is perceived to be more conducive online prescription drug sellers. The Online Pharmaceuticals Sales Measures Online Pharmaceuticals Sales Measures provides that, among others, online prescription drug sellers shall (1) ensure the accuracy and reliability of the source of prescription, (2) keep records of any prescription for at least five years and no less than one year after the expiration date of the prescription drugs, and (3) disclose safety warnings including “prescription drugs should only be purchased and used with prescriptions and guidance of licensed pharmacists” when displaying information of prescription drugs.

Regulations in relation to the Medical Insurance Program

Coverage of the national medical insurance program

The national medical insurance program was first adopted according to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》), further enlarged the coverage of the basic medical insurance program, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. In addition, on January 3, 2016, the Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) issued by the State Council required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees.

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Medical Insurance Catalogue

According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) or the NRDL Administrative Measures, which promulgated by the NHSA, on July 30, 2020 and took effect on September 1, 2020, the scope of drugs covered by the basic medical insurance shall be administered through a reimbursement drug list.

The National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List (the “NRDL”), which promulgated by the NHSA and the Ministry of Human Resources and Social Security and took effect on November 27, 2024, sets forth the payment standard for pharmaceutical products under the basic medical insurance, work-related injury insurance and maternity insurance funds. The local government shall strictly implement the NRDL and shall not adjust the contents contained in the NRDL at their own discretion. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs, while List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs.

According to the NRDL Administrative Measures, a Provincial Reimbursement Drug List (“PRDL”) must be made by the provincial healthcare security authorities. Patients purchasing List A drugs can directly obtain reimbursement under the basic medical insurance program. Patients purchasing List B drugs shall pay a certain percentage of the purchase price first and then obtain reimbursement under the basic medical insurance program.

National Essential Drug List

On August 18, 2009, the Ministry of Health (the “MOH”) and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Drug List (《國家基本藥物目錄管理辦法(暫行)》), which was amended on February 13, 2015, and the Guidelines on the Implementation of the National Essential Drug List System (《關於建立國家基本藥物制度的實施意見》), which aims to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National Essential Drug List. The NHC promulgated the National Essential Drug List (2018) (《國家基本藥物目錄(2018年版)》), the “National Essential Drug List”) on September 30, 2018, replacing the National Essential Drug List (2012) (《國家基本藥物目錄(2012年版)》) which was promulgated on March 13, 2013. According to these regulations, basic healthcare institutions funded by government shall store up and use drugs listed in National Essential Drug List. The drugs listed in National Essential Drug List shall be purchased by centralised tender process and shall be subject to the price control by the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會(the “NDRC”)). Remedial drugs in the National Essential Drug List are all listed in the Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

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Laws and Regulations on Intellectual Properties

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001, last amended on December 11, 2023 and became effective on January 20, 2024. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, “invention”, “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is 20 years, the duration of a patent right for “utility model” is 10 years, and the duration of a patent right for “design” is 15 years, from the date of application. According to the Patent Law of the PRC, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in comply with provisions of the relevant international treaty participated by the PRC.

Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and last amended on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

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Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and became effective on November 1, 2019, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided in accordance with applicable laws.

Copyright

Copyright in the PRC is primarily protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013. These law and regulation provide provisions on the classification of works and the obtaining and protection of copyright.

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC. Communications administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of "first apply, first register." A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

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Laws and Regulations on Labor and Employee Incentives

Labor, Social Insurance and Housing Provident Funds

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC in July 1994 and last amended and came into effect in December 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC in June 2007 and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages shall not be lower than local minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC in October 2010 and last amended and came into effect in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and last amended in March 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and last amended in March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the “Prevention and Control of Occupational Diseases Law”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

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Employee Stock Incentive Plans

On February 15, 2012, SAFE issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “Share Incentive Rules”). Under the Share Incentive Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC domestic company participating in such stock incentive plan, and complete certain procedures. In addition, the STA has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The domestic qualified agent has obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income tax of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC domestic companies fail to withhold, their individual income tax according to relevant laws, rules and regulations, the PRC domestic companies may face sanctions imposed by the tax authorities or other relevant PRC government authorities.

Laws and Regulations on Environmental Protection, Health and Safety

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) (“the Environmental Protection Law”), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the

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environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》) (“the Environmental Impact Appraisal Law”), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Completion and Acceptance

The Interim Measures for Acceptance of Environmental Protection upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》), promulgated and implemented by the former Ministry of Environmental Protection (now the MEE) on November 20, 2017, regulate the procedures and standards for environmental protection acceptance by construction entities upon the completion of construction projects.

Fire Prevention

According to the Fire Prevention Law of the PRC (《中華人民共和國消防法》), promulgated by the SCNPC on April 29, 1998 and last amended with effect from April 29, 2021, design and construction of the fire control facilities for a construction work shall comply with the national fire control technical standards. The developer, designer, constructors and project supervisor of a construction project shall be responsible for the quality of the design and construction of the fire control facilities for the construction work according to the relevant laws. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business.

Management of Waste Discharge

Pursuant to the Catalog of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the Ministry of Ecology and Environment of the PRC and became effective on December 20, 2019, the State implements the primary management, simplified management and registration management of pollutant discharge permits based on the pollutant production, emission amount and the extent of environmental impact of the pollutant discharge entities. A pollutant discharge unit under registration management does not need to apply for a pollutant discharge license.

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Pursuant to the Regulations on the Administration of Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021 and became effective on March 1, 2021, based on the quantity of pollutants generated and discharged, their impacts on the environment and other factors, categorical administration of pollutant discharge permit system is implemented to regulate pollutant-discharging entities: (1) key administration of pollutant discharge permits shall be implemented for pollutant discharging entities which generate and discharge relatively large quantities of pollutants or have a relatively serious impact on the environment; and (2) administration of pollutant discharge permits shall be simplified for pollutant-discharging entities which generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment. The entities that generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment shall fill in the waste discharge registration form (排污登記表) and are no longer required to obtain a waste discharge license (排污許可證). Entity that is required to fill in the waste discharge registration form shall report the basic information, waste discharge destination, waste discharge standards implemented, waste prevention and control measures adopted and other information to the national waste discharge license information platform. If the information reported is changed, it shall be changed in the platform within 20 days as of the date when such change occurs.

Laws and Regulations on Foreign Investment

On March 15, 2019, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “Foreign Investment Law”) was promulgated by the NPC. The Foreign Investment Law took effect on January 1, 2020, and the Sino-Foreign Equity Joint Ventures Law of the PRC (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-Owned Enterprises Law of the PRC (《中華人民共和國外資企業法》) and the Sino-Foreign Cooperative Joint Ventures Law of the PRC (《中華人民共和國合作經營企業法》) were abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors, while the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC (《中華人民共和國公司法》) and other laws.

The PRC implements a pre-access national treatment plus negative list management system for foreign investment, which means that foreign investors and their investments are given treatment no less favourable than that accorded to domestic investors and their investments at the stage of investment access; the so-called negative list refers to the special access management measures that the State has stipulated to be applied to foreign investment in specific areas, and the State grants national treatment to foreign investment that is not on the negative list.

The Catalogue of Industries Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) issued by the NDRC and the MOFCOM on October 26, 2022 (effective January 1, 2023), and the Special Administrative Measures for Foreign Investment Entry (Negative List) (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》)

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issued by the NDRC and the MOFCOM on September 26, 2024 (the “Negative List”), which became effective on November 1, 2024) together constitute the catalogue of industries encouraging foreign investment and the special administrative measures for foreign investment access to industries restricted or prohibited for foreign investment, of which the Negative List has uniformly listed the special administrative measures in respect of foreign investment access, such as shareholding requirements and senior management requirements. Fields outside the Negative List are managed in accordance with the principle of consistency between domestic and foreign investments. Domestic enterprises engaging in businesses in the areas of investment prohibited by the Negative List that issue shares abroad and list them for trading shall be subject to the examination and consent of the relevant competent state authorities. Foreign investors shall not participate in the operation and management of the enterprise, and the proportion of their shareholding shall be implemented with reference to the relevant provisions on the management of domestic securities investment by foreign investors.

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the MOFCOM. The foreign investment information reporting shall be subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System, and the reporting methods include initial reports, change reports, cancelation reports, and annual reports.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

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On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) (“the SAFE Circular 59”), which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) on February 13, 2015, which was partially abolished on December 30, 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 10, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (“the SAFE Circular 21”), which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (“the SAFE Circular 19”) promulgated on March 30, 2015, coming effective on June 1, 2015, partially abolished on December 30, 2019 and partially amended on March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises

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are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on lent to a third party; and (d) to purchase real estate not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (“the SAFE Circular 16”), which came into effect on the same day and was partially amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》) promulgated by the SAFE on December 4, 2023. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties). However, there remain substantial uncertainties with respect to SAFE Circular 16’s interpretation and implementation in practice.

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020) and was partially amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》) promulgated by the SAFE on December 4, 2023. This notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors’ security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item by item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

Taxation

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (“the EIT Law”), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) (“the Implementation

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Rules”), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

Value-Added Tax (the “VAT”)

The major PRC law and regulation governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the Ministry of Finance (中華人民共和國財政部) (the “MOF”), came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the STA issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

On December 25, 2024, the SCNPC promulgated the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》), which will become effective on January 1, 2026, and the Interim Regulations of the PRC on Value-Added Tax will be abolished.

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Laws and Regulations on Information Security and Data

Privacy Data Security and Data Export

The SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) on June 10, 2021, which became effective from September 1, 2021, for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

On December 28, 2021, the Cyberspace Administration of China (the “CAC”) and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “Cyber Review Measures”), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the “CIIO”) (關鍵信息基礎設施運營者) or the data processing activities conducted by a network platform operator (網絡平台運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if such governmental authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security.

According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) issued by the CAC on July 7, 2022 and effective on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the CIIO or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) issued by the CAC on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (i) it is not a CIIO; (ii) it has processed the personal information of

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less than one million individuals; (iii) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (iv) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year. In addition, the Measures for Standard Contract for Outbound Transfer of Personal Information require that all Outbound Transfers of personal information that have been carried out before June 1, 2023 and do not comply with the provisions of the Measures for Standard Contract for Outbound Transfer of Personal Information be rectified within 6 months.

According to the Provisions on Promoting and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), which was promulgated by the CAC on March 22, 2024 and came into effect on the same day, if the data have not been informed or publicly announced as important data by relevant departments or regions, data handlers are not required to declare security assessment for cross-border provision of the data as important data.

Personal Information Protection

According to the Civil Code of the PRC (《中華人民共和國民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people's personal information, they should obtain it in accordance with the law, ensure the security of the information, and must not illegally collect, use, process, or transmit other people's personal information or illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) promulgated by the SCNPC on August 20, 2021 and implemented on November 1, 2021 further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

According to the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) promulgated by the SCNPC on November 7, 2016 and effective on June 1, 2017, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect, and are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified, and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

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Laws and Regulations on Overseas Securities Offering and Listing by Domestic Companies

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improves and reforms the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and regulates both direct and indirect overseas offering and listing of PRC domestic companies’ securities. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in mainland China. In addition, the overseas securities offering and listing will be considered an indirect overseas offering by a PRC domestic company if the issuer meets both of the following criteria: (i) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by a domestic company; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China.

Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

H-share Full Circulation

“Full circulation” means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》) (the “Guidelines for the Full Circulation”), which was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》).

According to the Guidelines for the Full Circulation, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding

REGULATORY OVERVIEW

H-share listed company may be entrusted to file the said application for full circulation. To apply for full circulation, an H-share listed company shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures. After the application for full circulation has been approved by the CSRC, the H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with CSDCC of the shares related to the application has been completed.

On December 31, 2019, CSDCC and the Shenzhen Stock Exchange (“SZSE”) jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股“全流通”業務實施細則》) (the “Measures for Implementation”). The businesses in relation to the H-share full circulation business, such as cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. are subject to the Measures for Implementation.

On September 20, 2024, the Shenzhen Branch of CSDC issued the Guidelines to the Program for “Full Circulation” of H-shares of Shenzhen Branch of China Securities Depository and Clearing Corporation Limited (《中國證券登記結算有限責任公司深圳分公司H股“全流通”業務指南》), which are applicable to the business preparation, cross-border share transfer registration and overseas centralized custody, the initial maintenance of details of domestic shareholding and the maintenance of its changes, corporate actions, clearing, settlement and risk management measures. On the same day, China Securities Depository and Clearing (Hong Kong) Company Limited issued the H-Share Full Circulation Business Guide of China Securities Depository and Clearing (Hong Kong) Limited (《中國證券登記結算(香港)有限公司H股“全流通”業務指南》), which is applicable to businesses such as share custody and depository, agent service, arrangement for settlement and delivery, and risk management measures.

OVERVIEW OF LAWS AND REGULATIONS IN THE REPUBLIC OF UZBEKISTAN

Uzbekistan is a country with consumer-focused legislation. The primary governmental authority overseeing healthcare in Uzbekistan is the Ministry of Health (the “**Ministry of Health**”). In addition, the Ministry is involved in the formulation and execution of governmental initiatives related to pharmaceuticals and pharmaceutical activities. It is responsible for licensing pharmaceutical operations, as well as for the state registration and quality control of medicines, medical devices and equipment.

Product Liability and Safety

Product liability is generally regulated by the Law “On Consumer Protection” No. 221-I dated 26 April 1996 (as amended) (the “**Consumer Protection Law**”) and the Law “On Technical Regulation” ZRU-819 dated 27 February 2023 (as amended). Product liability may arise from contract, tort or breach of statutory duties.

REGULATORY OVERVIEW

The Law “On Protection of Public Health” No. 265-I dated 29 August 1996 (as amended) provides an additional framework for pharmaceutical safety and includes provisions on:

- state control over drug quality;
- licensing requirement for pharmaceutical activity.

The Law “On Medicines and Pharmaceutical Activity” is the primary document governing pharmaceutical products. It establishes:

- quality and safety requirements for pharmacological or medicinal products;
- requirements for preclinical and clinical trials;
- state registration requirement for drugs, medical devices, and medical equipment;
- pharmacovigilance obligations.

Consumer Protection

The Consumer Protection Law provides the basic framework for product liability claims and consumer rights.

In accordance with Article 12 of the Consumer Protection Law, if it is found that the use, storage, transportation or disposal of goods caused or may cause harm to life, health, property of the consumer or the environment, the manufacturer (contractor, seller) shall be obliged to immediately suspend their production (sale) until the elimination of the causes causing harm, take measures to withdraw them from the market and recall them from consumers.

In the event that the causes of harm cannot be eliminated, the manufacturer (contractor, seller) shall be obliged to remove such goods from production whereby the goods of medical, food purpose and household chemistry are subject to mandatory disposal by the seller or manufacturer. In case of non-fulfillment by the seller or manufacturer (contractor) of these obligations, state regulatory authorities will enforce the withdrawal, cessation of activities, and product recall.

Losses caused to the consumer in connection with the recall of goods shall be subject to compensation by the manufacturer (contractor, seller) in full. If the manufacturer (contractor, seller) has taken all necessary measures to recall the goods with dangerous properties, it shall be released from liability for damage caused due to the fact that the consumer continued to use the said goods.

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Article 20 of the Consumer Protection Law specifically addresses material liability for defective products that cause harm. Damage caused to life, health or property of the consumer due to design, manufacturing, prescription and other defects of goods, as well as the use of materials, equipment, devices, instruments, tools, devices or other means that do not ensure the safety of life, health or property of the consumer, shall be subject to compensation by the seller (manufacturer, contractor).

Liability arises regardless of the existence of contractual relationships. This implies that claims against manufacturers, sellers, and contractors, upon consumer’s choice, may be initiated not only by the buyers of the goods, but also by third parties. The seller, manufacturer or contractor shall be released from liability if it proves that the damage was caused due to force majeure or violation by the consumer of the established rules of use, storage or transportation.

Moral harm caused to the consumer as a result of violation of his/her rights shall be subject to compensation by the inflictor of harm in the presence of its guilt. The amount of compensation for moral harm shall be determined by the court.

Licensing

Pursuant to the Law “On licensing, permitting and notification procedures” No. 701 dated July 14, 2021, a business activity related to pharmaceutical products is subject to obtaining a state license. This license has four types of sub-licenses:

Sublicense Type	Authorized Body in the field
production of medicines manufacture of medicines wholesales of medicines	The Agency for the Development of the Pharmaceutical Industry under the Ministry of Health of the Republic of Uzbekistan
retail sale of medicines and medical devices (except for retail sale of ophthalmic medical devices)	Regional subdivisions of the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health of the Republic of Uzbekistan

State Registration (Marketing Authorization)

Medicines, medical devices and medical equipment are authorized for use in medical practice, as a general rule, after their state registration.

State registration is mandatory for:

- medicines (except for medicinal substances (substances) used in the production of medicinal products);

REGULATORY OVERVIEW

- new combinations of medicines registered in the Republic of Uzbekistan;
- medicines previously registered in the Republic of Uzbekistan, but produced in other dosage forms, dosages, or by a different manufacturer;
- medical devices;
- medical equipment.

State registration of medicines, medical devices and medical equipment is carried out by the Ministry of Health.

Registered medicines, medical devices and medical equipment are included in the State Register of medicines, medical devices and medical equipment authorized for use in medical practice. A registration certificate is issued as a proof of confirmation.

In accordance with the Resolution of the President of Uzbekistan No. PP-411 dated October 26, 2022, all new medicines:

- undergo state registration on the basis of a positive result of clinical trials. Herewith, state registration of certain medicines without clinical trials is carried out in accordance with the procedure established by the Ministry of Health.
- undergo state registration in the Republic of Uzbekistan after on-site examination of compliance of production conditions with the requirements of “Good Manufacturing Practice — GMP”.

Packaging and Labelling

Mandatory labeling in the state language applies to goods that are packaged for consumers, where the packaging is an integral part of the product and is included in its overall value when delivered to retail markets. Realization of the goods not marked in the state language is prohibited.

In accordance with the Resolution of the Cabinet of Ministers of Uzbekistan “On improving the procedure for labeling and customs clearance of certain types of imported consumer goods” No. 22 dated February 5, 2014, import of medicines having consumer packaging (tare) is carried out with mandatory labeling in Uzbek.

Labeling of imported medicinal products is carried out by inserting information for the consumer in the consumer package (tare) in the state language in the form of a leaflet-insert, without additional marking on the package. In case of absence of labeling in Uzbek, placed by the manufacturer, it is allowed to label imported medicinal products after their importation into the territory of the Republic of Uzbekistan, during storage in the customs warehouse, by placing inserts in Uzbek in the group package of corresponding units.

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The text of labeling of medicinal products in the state language is approved by the Main Department for Quality Control of Medicines and Medical Equipment of the Ministry of Health.

Mandatory Digital Labelling (Track and Trace System)

In accordance with the Resolution of the Cabinet of Ministers of Uzbekistan “On the introduction of a system of mandatory digital labeling of certain types of goods” No. 737 dated November 21, 2020, medicines are required to have mandatory digital labeling (QR code) from the National Digital Labeling System “Asl belgisi”.

QR codes are unique identifiers assigned to each unit of a medicinal product, enabling the tracking and tracing of their distribution in the market. These codes must be acquired either by manufacturers or importers.

Certification

According to Article 6 of the Law of the Republic of Uzbekistan “On Standardization” No. 1002-XII dated 28 December 1993, products imported to Uzbekistan cannot be used for their intended purpose if their compliance with technical regulations and standards in force in Uzbekistan is not confirmed by the certification of conformity.

According to Article 12 of the Law of the Republic of Uzbekistan “On Certification of Products and Services” No. 1006-XII dated 28 December 1993, products subject to mandatory certification may not be sold on the territory of Uzbekistan if:

- they have not been submitted for certification;
- they have not passed certification due to non-compliance with certification requirements;
- the certificate has expired or been suspended (revoked).

Under the Resolution of the Minister of Healthcare of Uzbekistan “On approval of the rules for certification of pharmaceutical products” No. 3386 dated September 12, 2022, certification of pharmaceutical products is carried out after their state registration.

Certification bodies assess the compliance of pharmaceutical products with the requirements for labeling, packaging and other indicators in accordance with the requirements established by regulatory documents.

Pricing

Uzbekistan employs a combination of reference pricing and maximum markup regulations for pharmaceuticals.

REGULATORY OVERVIEW

In accordance with the Resolution of the Cabinet of Ministers “On measures to implement the Law of Uzbekistan No. ZRU-399 dated January 4, 2016 «On amendments and additions to the Law of Uzbekistan ‘On Medicines and Pharmaceutical Activities’»” No. 185 dated May 6, 2017, maximum trade markups are set as follows:

- for wholesale distribution medicines and medical devices – fifteen percent (15%) of the purchase price;
- for retail sale of medicines and medical devices – twenty percent (20%) of the distribution price.

Under the reference pricing framework, a local reference price must be established for each medicine. In accordance with the Resolution of the President of Uzbekistan “On additional measures to deepen reforms in the pharmaceutical industry of the Republic of Uzbekistan” No. 4554 dated December 30, 2019, this price is determined based on the original price from the manufacturing country, as well as prices in Uzbekistan and ten designated reference countries. Importation of medicines into Uzbekistan is prohibited if their prices exceed the established reference price.

Failure to adhere to the pricing mechanism established by Uzbek legislation may lead to suspension or even termination of the state license for pharmaceutical activity.

Uzbek Import Regulations

Customs legislation in Uzbekistan is governed by national laws as well as international agreements. Uzbekistan joined the Eurasian Economic Union (EEU) as an observer state in 2020, and intends to maintain its status as a neutral observer, which was disclosed on October 17, 2024. The country’s customs procedures are primarily regulated by the Customs Code of the Republic of Uzbekistan (the “**Customs Code**”) and regulatory acts.

On 21 December 1994, Uzbekistan became a member of the World Trade Organization (WTO) Observer Government. The country formally applied for WTO membership in 1994 and is currently in the process of accession negotiations, with the most recent Working Party meeting held on December 2024. Uzbekistan’s commitments and obligations will be established in its future Protocol of Accession to the WTO, which is still under negotiation.

Uzbekistan participates in several major international customs conventions, including the International Convention on the Harmonized Commodity Description and Coding System (since 2000), the Convention on Temporary Admission (Istanbul Convention – since 2020), and the International Convention on the Simplification and Harmonization of Customs Procedures (Revised Kyoto Convention – since 2021). Also, Uzbekistan stands as a member of the World Customs Organization since 1992.

REGULATORY OVERVIEW

All cross-border transfers of goods in Uzbekistan are conducted under specific customs regimes as defined by Article 25 of the Customs Code. Each customs regime establishes distinct terms for clearance.

Imported goods can be declared either by the individual or legal entity transporting the goods or by a customs broker. The entity or person making the declaration must fulfill all obligations and bears full responsibility provided under the Uzbek legislation, regardless of whether this person or entity is the importer or customs broker.

Import of goods into Uzbekistan is carried out on the basis of an import contract and importer’s invoice.

As per the Regulation on the Procedure for Monitoring and Control of Foreign Trade Operations, approved by the Resolution of the Cabinet of Ministers No. 283 on May 14, 2020 (the “**Regulation No. 283**”), all cross-border contracts, including import contracts, must be registered in the Unified Electronic Information System for Foreign Trade Operations (“**Unified System**”), a requirement to be fulfilled by the residents of Uzbekistan with the use of a local e-signature.

In the course of customs monitoring, the information provided by importers – residents of Uzbekistan in the Unified System is checked against the customs cargo declarations. This includes verifying the compliance of goods in terms of quantity and quality with the information specified in the Unified System, as well as ensuring compliance of contracts with legal requirements and identification of overdue receivables.

Pursuant to clauses 23-24 of the Regulation No. 283, goods must be imported (i.e., registered in the customs regime of import) or payments returned within 180 days of payment for imports, while export revenues must be received within 180 days of export registration.

The violation of the above requirement is considered an overdue receivable that is subject to the following penalties under Article 11(1) of the Law “On currency regulation” No. 573 dated October 22, 2019:

- equivalent of 5% of the overdue receivables amount – for delays of up to 360 days from the payment date or export to a non-resident;
- an additional equivalent of 10% of the overdue receivables amount – for delays from 360 to 545 days from the payment date or export to a non-resident;
- an additional equivalent of 35% of the overdue receivables amount – for delays exceeding 545 days from the payment date or export to a non-resident.

Please note that currently, overdue receivables are considered a quite serious violation leading not only to penalties but also to complications with payments under other cross-border contracts.

REGULATORY OVERVIEW

Anti-dumping Regulations

The Law of the Republic of Uzbekistan "On Safeguard, Anti-dumping and Countervailing Measures" No. 554-II dated December 11, 2003, establishes the legal basis for implementing trade protection measures against imports from foreign countries.

Anti-dumping duties can be imposed on goods by decision of the Cabinet of Ministers of the Republic of Uzbekistan, if the results of investigation of the authorized body establish that import of goods at dumping prices causes serious damage or threatens to cause serious damage to a domestic industry.

Anti-dumping duties in Uzbekistan are imposed on goods imported at dumping prices when an investigation by the authorized body establishes that the dumping margin exceeds two percent (2%) of the export price, or when the volume of imports at dumping prices is considered significant.

The volume of imports at dumping prices from a supplier country under investigation is considered significant if:

- it exceeds three percent (3%) of the total volume of imports of similar goods into the Republic of Uzbekistan, or
- when the combined volume of imports at dumping prices from countries whose individual share is less than three percent (3%) exceeds seven percent (7%) of the total volume of imports of similar goods into the Republic of Uzbekistan.

Anti-dumping duties in Uzbekistan are imposed for a maximum period of five years from initial application or last review. This period can be extended if a review determines that terminating the duty would lead to continued dumping and damage to the domestic industry.

The anti-dumping investigation may be stopped and the duties may not be imposed if the exporter agrees in writing (price undertaking) to revise prices or stop exporting to Uzbekistan below normal value as sufficient to eliminate damage to the domestic industry.

Tax

Under Customs Code, when transferring goods across the customs border and in other cases stipulated by Uzbek legislation, the following customs payments shall be paid:

- customs duty;
- value added tax (12%);
- excise tax;
- customs processing fees.

Other customs payments may be established by the legislation.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

Our Company was established in the PRC as a limited liability company on January 21, 2013 and converted into a joint stock company with limited liability on April 28, 2023.

As a fully integrated biopharmaceutical company, we are dedicated to the discovery, development, and commercialization of innovative small molecule drugs. With mission to innovate for better health and quality of life, we strive to address the diverse and evolving patient needs in our strategically focused therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health.

Over the past 12 years, we have not only established end-to-end capabilities spanning the entire industry value chain from research and clinical development to manufacturing and commercialization, but also developed a distinguished innovative pipeline of nine product candidates, including three Core Products, VV116, LV232 and TPN171 each with first- or best-in-class potential.

Dr. Shen and Dr. Tian are founders of our Company. Dr. Shen, our Controlling Shareholder, is a renowned scientist in development of small molecule drugs with more than 30 years of industry experience and holds prestigious academic and research positions, including as a honorary professor of Samarkand State University. As our founder, Dr. Shen contributed substantial resources and expertise during the initial stage of our operations and played a vital role in forming our business directions and strategies. We benefit from the high-level guidance and advice from Dr. Shen as our Controlling Shareholder. Dr. Tian, chairman of the Board, executive Director, chief executive officer and general manager of our Company has over 20 years of industry experience and has led several national research initiatives. Dr. Tian brings extensive experience and expertise that leads our strategic direction, research and development, and operational decisions, driving our commitment to innovation.

For details of the biographical background and relevant industry experience of Dr. Tian, see “Directors, Supervisors and Senior Management” in this document.

BUSINESS DEVELOPMENT MILESTONES

The following table summarizes the key milestones in our business development:

Year	Milestone
2013	Our Company was established in the PRC
2014	We submitted the IND application for TPN171
2018	We submitted the IND application for TPN102 and received clinical trial approval
2019	We began constructing Lianyungang Facility

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2020	<p>We obtained the approval for Phase II clinical trial for TPN171</p> <p>We completed Angel Round Financing and raised RMB80 million</p>
2021	<p>We submitted the IND application for VV116 in the PRC and secured marketing approval in Uzbekistan for the treatment of moderate and severe COVID-19 in Uzbekistan</p> <p>We completed Series A Financing and raised RMB20 million</p>
2022	<p>We completed Series A+ Financing and Series B Financing raised RMB50 million and RMB200 million</p>
2023	<p>We converted into a joint-stock liability company</p> <p>Vigonvita Lianyungang obtained a Drug Manufacturing License</p> <p>Clinical trial approvals were obtained for VV116 and VV119 with the indications of RSV infection and schizophrenia, respectively</p> <p>We submitted an NDA application for TPN171 (ED indication)</p> <p>We submitted an ANDA application for Rebamipide Tablets</p> <p>Dapoxetine hydrochloride tablets were approved in the PRC</p> <p>We recorded RMB196.2 million revenue from the out-licensing of VV116 for the treatment of COVID-19</p>
2024	<p>We completed Series C Financing and raised RMB160 million</p> <p>We received the approval from the ethics committee for conducting a Phase I clinical trial of VV261 in healthy subjects</p> <p>We obtained marketing approval of rebamipide from the NMPA</p> <p>We received the approval for conducting a Phase II clinical trial of LV232 in depression patients from the ethics committee</p>
2025	<p>We completed two Phase I clinical studies of LV232 in healthy subjects</p> <p>We published the relevant information of the Phase II clinical trial of LV232 for the treatment of depression through the official website of the CDE</p>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR GROUP

As of the Latest Practicable Date, our Group comprised of our Company and six subsidiaries. Our Company served as the centralized management platform and R&D center of our Group where we run our overall business operation and our subsidiaries focus on daily business operation of our Group. The details of our subsidiaries as of the Latest Practicable Date are set forth below:

Subsidiaries	Place of establishment	Date of establishment	Registered capital/issued share capital	Equity interest attributable to our Group	Principal business activities
Vigonvita Lianyungang	PRC	December 6, 2019	RMB100,000,000	100%	Production and commercialisation of innovative drugs
Nantong Hefeng	PRC	October 10, 2020	RMB10,204,082	51%	R&D, and commercialisation of innovative drugs
Vigonvita Shanghai	PRC	August 19, 2022	RMB10,000,000	100%	R&D of innovative drugs
Yingjiu Health	PRC	December 6, 2023	RMB1,000,000	100%	Sales and marketing management
Qingdao Antai	PRC	April 28, 2024	RMB50,000,000	90%	Production and commercialisation of innovative drugs
Vigonvita Tashkent	Uzbekistan	May 12, 2021	UZS5,544,916,636 (equivalent to USD500,000)	100%	Sales of pharmaceutical drugs

MAJOR ACQUISITIONS, DISPOSALS AND MERGERS

During the Track Record Period and up to the Latest Practicable Date, we did not conduct any major acquisitions, disposals or mergers that we consider to be material to us.

ESTABLISHMENT AND DEVELOPMENT OF OUR COMPANY

(1) Establishment of Our Company

On January 21, 2013, our Company was established as a limited liability company under the laws of the PRC, with an initial registered capital of RMB5 million. Upon the establishment, the registered capital of our Company was owned as to 98% and 2% by Dr. Shen and his spouse, Ms. Jin Jie, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(2) Subsequent Capital Changes and Equity Transfers

(a) Equity Transfer in January 2019

On November 3, 2018, Suzhou Nanbowan Enterprise Management Consulting Partnership (Limited Partnership) (蘇州南博萬企業管理諮詢合夥企業(有限合夥)) (“**Suzhou Nanbowan**”) entered into an equity transfer agreement with Dr. Shen, pursuant to which, Dr. Shen agreed to transfer a registered capital of our Company of RMB750,000 (representing approximately 15.00% equity interest in our Company at the time) to Suzhou Nanbowan for a consideration of RMB750,000. Suzhou Nanbowan was then owned by Dr. Tian and Ms. Jin Qing (金青) (Ms. Jin Jie’s sister) as to 80% and 20% respectively. Upon establishment of the Company, Dr. Shen reserved such equity interest for subscription by the founding employees. In 2019, as the Company intended to conduct the Angel Round Financing, the transfer of such equity interest was carried out to streamline the shareholding structure of the Company.

Upon the completion of such equity transfer on January 9, 2019, the shareholding structure of our Company was set forth in the table below:

Shareholders	Registered capital subscribed for	Approximate corresponding equity interest in our Company
	(RMB)	(%)
Dr. Shen	4,150,000	83.00
Ms. Jin Jie	100,000	2.00
Suzhou Nanbowan	750,000	15.00
Total	5,000,000	100.00

(b) Angel Round Financing

In November 2018, Gongqingcheng Zhongcai Qihu Financial Control Phase II Internet Industry Investment Center (Limited Partnership) (共青城中財奇虎金控二期互聯網產業投資中心(有限合夥)) (“**Zhongcai Qihu**”) entered into an investment agreement with our Company, Dr. Shen and Ms. Jin Jie, pursuant to which, Zhongcai Qihu agreed to subscribe for an increased registered capital of RMB192,308 of our Company (representing approximately 3.33% equity interest in our Company upon completion of the capital increase) for a consideration of RMB20 million.

Pursuant to an investment agreement entered in January 2019 and a supplemental investment agreement entered in August 2020 entered into by and among Ganzhou Qizhi Huikang Equity Investment Fund Management Partnership (Limited Partnership) (贛州啟智匯康股權投資基金管理合夥企業(有限合夥)) (formerly known as Rizhao Qizhi Huikang Equity Investment Fund Management Partnership (Limited Partnership) (日照啟智匯康股權投資基金管理合夥企業(有限合夥)) (“**Qizhi Huikang**”), our Company, Dr. Shen and Ms. Jin Jie, Qizhi Huikang agreed to subscribe for the increased registered capital of RMB336,538 of our Company (representing approximately 5.83% equity interest in our Company upon completion of the capital increase) for a consideration of RMB35 million.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

In March 2020, Suzhou Xieyao Kexin Venture Capital Partnership Enterprise (Limited Partnership) (蘇州協耀科新創業投資合夥企業(有限合夥)) (“**Xieyao Kexin**”) entered into an investment agreement with our Company, Dr. Shen, Ms. Jin Jie and Suzhou Nanbowan, pursuant to which, Xieyao Kexin agreed to subscribe for the increased registered capital of RMB192,308 of our Company (representing approximately 3.33% equity interest in our Company upon completion of the capital increase) for a consideration of RMB20 million.

In June 2020, Suzhou Meilingge Business Consulting Partnership Enterprise (Limited Partnership) (蘇州美靈格商務諮詢合夥企業(有限合夥)) (“**Suzhou Meilingge**”) entered into an investment agreement with our Company, Dr. Shen and Ms. Jin Jie, pursuant to which, Suzhou Meilingge agreed to subscribe for an increased registered capital of RMB48,077 of our Company (representing approximately 0.83% equity interest in our Company upon completion of the capital increase) for a consideration of RMB5 million.

The then shareholders of our Company resolved to increase the registered capital of our Company from RMB5,000,000 to RMB5,769,231 on June 28, 2020 for subscription by Zhongcai Qihu, Qizhi Huikang, Xieyao Kexin and Suzhou Meilingge pursuant to the relevant investment agreements (the “**Angel Round Financing**”).

Upon the completion of the Angel Round Financing, the shareholding structure of our Company was set forth in the table below:

<u>Shareholders</u>	<u>Registered capital subscribed for</u>	<u>Approximate corresponding equity interest in our Company</u>
	<i>(RMB)</i>	<i>(%)</i>
Dr. Shen	4,150,000	71.94
Ms. Jin Jie	100,000	1.74
Suzhou Nanbowan	750,000	13.00
Qizhi Huikang	336,538	5.83
Zhongcai Qihu	192,308	3.33
Xieyao Kexin	192,308	3.33
Suzhou Meilingge	48,077	0.83
Total	<u>5,769,231</u>	<u>100.00</u>

(c) Equity Transfer to the Employee Incentive Platform in September 2021

On August 13, 2021, the then shareholders of our Company approved the proposed transfer of a registered capital of our Company of RMB865,385 (representing approximately 15.00% equity interest in our Company at the time) from Dr. Shen to Suzhou Hesheng, being the Employee Incentive Platform established for granting employee incentives, at nominal consideration. Accordingly, on August 30, 2021, Dr. Shen entered into an equity transfer agreement with Suzhou Hesheng.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon the completion of such equity transfer on September 15, 2021, the shareholding structure of our Company was set forth in the table below:

Shareholders	Registered capital subscribed for	Approximate corresponding equity interest in our Company
	(RMB)	(%)
Dr. Shen	3,284,615	56.94
Ms. Jin Jie	100,000	1.74
Suzhou Hesheng	865,385	15.00
Suzhou Nanbowan	750,000	13.00
Qizhi Huikang	336,538	5.83
Zhongcai Qihu	192,308	3.33
Xieyao Kexin	192,308	3.33
Suzhou Meilingge	48,077	0.83
Total	<u>5,769,231</u>	<u>100.00</u>

(d) Series A Financing

On September 15, 2021, Jiaying Yuhan Equity Investment Partnership Enterprise (Limited Partnership) (嘉興譽瀚股權投資合夥企業(有限合夥)) (“**Jiaying Yuhan**”) entered into an investment agreement with our Company and Dr. Shen, pursuant to which, Jiaying Yuhan agreed to subscribe for an increased registered capital of our Company of RMB96,154 (representing approximately 1.64% equity interest in our Company upon completion of the capital increase) for a consideration of RMB20 million. On the same date, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB5,769,231 to RMB5,865,385 for subscription by Jiaying Yuhan (the “**Series A Financing**”).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon the completion of the Series A Financing, the shareholding structure of our Company was set forth in the table below:

Shareholders	Registered capital subscribed for	Approximate corresponding equity interest in our Company
	(RMB)	(%)
Dr. Shen	3,284,615	56.00
Ms. Jin Jie	100,000	1.70
Suzhou Hesheng	865,385	14.75
Suzhou Nanbowan	750,000	12.79
Qizhi Huikang	336,538	5.74
Zhongcai Qihu	192,308	3.28
Xieyao Kexin	192,308	3.28
Jiaying Yuhan	96,154	1.64
Suzhou Meilingge	48,077	0.82
Total	<u>5,865,385</u>	<u>100.00</u>

(e) Series A+ Financing

On December 13, 2021, Jiaying Yuhan entered into an investment agreement with our Company and Dr. Shen, pursuant to which, Jiaying Yuhan agreed to subscribe for an increased registered capital of our Company of RMB69,459 (representing approximately 1.10% equity interest in our Company upon completion of the capital increase) for a consideration of RMB18 million.

On December 13, 2021, Shenzhen Ruikang Yuhong Win Win Investment Partnership (Limited Partnership) (深圳市銳康宇宏共贏投資合夥企業(有限合夥)) (“**Ruikang Yuhong**”) entered into an investment agreement with our Company and Dr. Shen, pursuant to which, Ruikang Yuhong agreed to subscribe for an increased registered capital of RMB84,894 of our Company (representing approximately 1.40% equity interest in our Company upon completion of the capital increase) for a consideration of RMB22 million.

On December 14, 2021, Suzhou Industrial Investment Innovation and Entrepreneurship Investment Partnership Enterprise (Limited Partnership) (蘇州產投創新創業投資合夥企業(有限合夥)) (“**Suzhou Industrial Investment**”) entered into an investment agreement with our Company and Dr. Shen, pursuant to which, Suzhou Industrial Investment agreed to subscribe for an increased registered capital of our Company of RMB38,588 (representing approximately 0.64% equity interest in our Company upon completion of the capital increase) for a consideration of RMB10 million.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

On December 22, 2021, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB5,865,385 to RMB6,058,326 for subscription by Jiaxing Yuhan, Ruikang Yuhong and Suzhou Industrial Investment pursuant to relevant investment agreements (the “**Series A+ Financing**”).

Upon the completion of the Series A+ Financing, the shareholding structure of our Company was set forth in the table below:

Shareholders	Registered capital subscribed for	Approximate corresponding equity interest in our Company
	(RMB)	(%)
Dr. Shen	3,284,615	54.22
Ms. Jin Jie	100,000	1.65
Suzhou Hesheng	865,385	14.28
Suzhou Nanbowan	750,000	12.38
Qizhi Huikang	336,538	5.56
Zhongcai Qihu	192,308	3.17
Xieyao Kexin	192,308	3.17
Jiaxing Yuhan	165,613	2.74
Ruikang Yuhong	84,894	1.40
Suzhou Meilingge	48,077	0.79
Suzhou Industrial Investment	38,588	0.64
Total	6,058,326	100.00

(f) Equity Transfer in February 2022

On January 19, 2022, Ganzhou Yufei Shanshui Equity Investment Partnership Enterprise (Limited Partnership) (贛州予飛杉水股權投資合夥企業(有限合夥)) (formerly known as Gongqingcheng Shanshui Equity Investment Partnership Enterprise (Limited Partnership) (共青城杉水股權投資合夥企業(有限合夥))) (“**Yufei Shanshui**”) entered into an equity transfer agreement with Qizhi Huikang, pursuant to which, Qizhi Huikang agreed to transfer a registered capital of our Company of RMB336,538 (representing approximately 5.56% equity interest in our Company at the time) to Yufei Shanshui for a consideration of RMB35 million.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon the completion of such equity transfer on February 16, 2022, the shareholding structure of our Company was set forth in the table below:

Shareholders	Registered capital subscribed for	Approximate corresponding equity interest in our Company
	(RMB)	(%)
Dr. Shen	3,284,615	54.22
Ms. Jin Jie	100,000	1.65
Suzhou Hesheng	865,385	14.28
Suzhou Nanbowan	750,000	12.38
Yufei Shanshui	336,538	5.56
Zhongcai Qihu	192,308	3.17
Xieyao Kexin	192,308	3.17
Jiaxing Yuhan	165,613	2.74
Ruikang Yuhong	84,894	1.40
Suzhou Meilingge	48,077	0.79
Suzhou Industrial Investment	38,588	0.64
Total	<u>6,058,326</u>	<u>100.00</u>

(g) Series B Financing

Pursuant to the investment agreements entered into among our Company, Dr. Shen and each of Hainan Junshi Phase I Equity Investment Fund Partnership Enterprise (Limited Partnership) (海南君實一期股權投資基金合夥企業(有限合夥)) (“**Hainan Junshi**”), Hangzhou Hemeng Medical Intelligence Equity Investment Partnership Enterprise (Limited Partnership) (杭州和盟醫智股權投資合夥企業(有限合夥)) (“**Hemeng Medical Intelligence**”), Suzhou Junding Changwang Entrepreneurship Investment Center (Limited Partnership) (蘇州君鼎長旺創業投資中心(有限合夥)) (“**Junding Changwang**”), Suzhou Xieyao Kesheng Entrepreneurship Investment Partnership Enterprise (Limited Partnership) (蘇州協耀科盛創業投資合夥企業(有限合夥)) (“**Xieyao Kesheng**”), Fujian Yide Equity Investment Partnership Enterprise (Limited Partnership) (福建宜德股權投資合夥企業(有限合夥)) (“**Fujian Yide**”) and Fuzhou Xindui Investment Partnership Enterprise (Limited Partnership) (福州鑫兌投資合夥企業(有限合夥)) (“**Fuzhou Xindui**”), Hainan Junshi, Hemeng Medical Intelligence, Junding Changwang, Xieyao Kesheng, Fujian Yide and Fuzhou Xindui subscribed for an increased registered capital of RMB302,916 in aggregate for a total consideration of RMB200 million (the “**Series B Financing**”).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

The respective subscription amount and consideration for each subscriber in the Series B Financing were as follows:

Subscribers	Amount of Increased registered capital subscribed	Consideration	Approximate corresponding equity interest in our Company (upon completion of the capital increase)
	(RMB)	(RMB)	(%)
Hainan Junshi	75,729	50,000,000	1.19
Hemeng Medical Intelligence	60,584	40,000,000	0.95
Junding Changwang	45,437	30,000,000	0.71
Xieyao Kesheng	45,437	30,000,000	0.71
Fujian Yide	45,437	30,000,000	0.71
Fuzhou Xindui	30,292	20,000,000	0.48

Upon the completion of the Series B Financing, the shareholding structure of our Company was set forth in the table below:

Shareholders	Registered capital subscribed for	Approximate corresponding equity interest in our Company
	(RMB)	(%)
Dr. Shen	3,284,615	51.63
Ms. Jin Jie	100,000	1.57
Suzhou Hesheng	865,385	13.60
Suzhou Nanbowan	750,000	11.79
Yufei Shanshui	336,538	5.29
Zhongcai Qihu	192,308	3.02
Xieyao Kexin	192,308	3.02
Jiaxing Yuhan	165,613	2.60
Ruikang Yuhong	84,894	1.33
Hainan Junshi	75,729	1.19
Hemeng Medical Intelligence	60,584	0.95
Suzhou Meilingge	48,077	0.76
Junding Changwang	45,437	0.71
Xieyao Kesheng	45,437	0.71
Fujian Yide	45,437	0.71
Suzhou Industrial Investment	38,588	0.61
Fuzhou Xindui	30,292	0.48
Total	6,361,242	100.00

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(h) Equity Transfers in March 2023

On January 5, 2023, an equity transfer agreement was entered into by and among Dr. Tian, Ms. Jin Qing and Suzhou Nanbowan, pursuant to which, Suzhou Nanbowan agreed to transfer registered capital of our Company of RMB600,000 and RMB150,000 (representing approximately 9.43% and 2.36% equity interest in our Company at the time) to Dr. Tian and Ms. Jin Qing at nominal consideration, respectively. The equity transfers was made to streamline the shareholding structure so as to allow Dr. Tian and Ms. Jin Qing to hold direct interests in the Company instead of through Suzhou Nanbowan.

Upon the completion of such equity transfers on March 10, 2023, the shareholding structure of our Company was set forth in the table below:

Shareholders	Registered capital subscribed for	Approximate corresponding equity interest in our Company
	(RMB)	(%)
Dr. Shen	3,284,615	51.63
Ms. Jin Jie	100,000	1.57
Suzhou Hesheng	865,385	13.60
Dr. Tian	600,000	9.43
Yufei Shanshui	336,538	5.29
Zhongcai Qihu	192,308	3.02
Xieyao Kexin	192,308	3.02
Jiaxing Yuhan	165,613	2.60
Ms. Jin Qing	150,000	2.36
Ruikang Yuhong	84,894	1.33
Hainan Junshi	75,729	1.19
Hemeng Medical Intelligence	60,584	0.95
Suzhou Meilingge	48,077	0.76
Junding Changwang	45,437	0.71
Xieyao Kesheng	45,437	0.71
Fujian Yide	45,437	0.71
Suzhou Industrial Investment	38,588	0.61
Fuzhou Xindui	30,292	0.48
Total	<u>6,361,242</u>	<u>100.00</u>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(i) Conversion into a Joint Stock Limited Company

Pursuant to the shareholders’ resolutions on March 27, 2023, all promoters (being all the then Shareholders) agreed to convert our Company from a limited liability company into a joint stock limited company with the registered capital of RMB6,361,242. According to a valuation report prepared by an independent valuer, the net asset value of our Company as of November 30, 2022 amounted to RMB183,061,754.35, of which, pursuant to the resolutions by the then shareholders of the Company, (i) RMB6,361,242 was converted into 6,361,242 Shares with a nominal value of RMB1.0 per Share; and (ii) the remaining amount of RMB176,700,512.35 was converted to capital reserve of our Company. Upon completion of the conversion, the share capital of our Company was RMB6,361,242 divided into 6,361,242 Shares with a nominal value of RMB1.00 each which were subscribed by all the then Shareholders in proportion to their respective equity interests in our Company before the conversion. The conversion was completed on April 28, 2023 when our Company obtained a new business license and was renamed as Vigonvita Life Sciences Co., Ltd. (蘇州旺山旺水生物醫藥股份有限公司).

(j) Share Transfer in May 2024

On May 10, 2024, an equity transfer agreement was entered into by and among Yufei Shanshui, Jiuzhou Ketou and Hubei Chuangxin Tongxiang Enterprise Management Partnership (Limited Partnership) (湖北創新同享企業管理合夥企業(有限合夥)) (“**Chuangxin Tongxiang**”), pursuant to which, Yufei Shanshui agreed to transfer 18,039 Shares and 2,775 Shares of our Company (representing approximately 0.27% and 0.04% equity interest in our Company at the time) to Jiuzhou Ketou and Chuangxin Tongxiang for a consideration of RMB6.5 million and RMB1 million, respectively (the “**May-2024 Transfer**”).

(k) Series C Financing

Pursuant to the share subscription agreements entered into by and among our Company, Dr. Shen and each of Ms. Jin Qing, Qingdao Bei’an Industrial Investment Holding Co., Ltd. (青島北岸產業投資控股有限公司) (“**Qingdao Bei’an**”), Hubei Jiuzhou Ketou Health Venture Capital Fund Partnership (Limited Partnership) (湖北九州科技健康創業投資基金合夥企業(有限合夥)) (“**Jiuzhou Ketou**”) and Qingdao Wangde Venture Capital Partnership Enterprise (Limited Partnership) (青島旺德創業投資合夥企業(有限合夥)) (“**Qingdao Wangde**”), Ms. Jin Qing, Qingdao Bei’an, Jiuzhou Ketou and Qingdao Wangde subscribed for an aggregated increased registered capital of RMB239,482 for a total consideration of RMB160 million (the “**Series C Financing**”).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

The respective subscription amount and consideration for each subscriber in the Series C Financing were as follows:

Subscribers	Number of Shares subscribed for	Consideration (RMB)	Shareholding percentage (upon completion of the capital increase) (%)
Ms. Jin Qing	14,968	10,000,000	0.22
Qingdao Bei'an	149,676	100,000,000	2.27
Jiuzhou Ketou	20,206	13,500,000	0.58
Qingdao Wangde	54,632	36,500,000	0.83

Upon the completion of the May-2024 Transfer and Series C Financing, the shareholding structure of our Company as of December 31, 2024 was set forth in the table below:

Shareholders	Number of Shares	Shareholding percentage (%)
Dr. Shen	3,284,615	49.76
Ms. Jin Jie	100,000	1.52
Suzhou Hesheng	865,385	13.11
Dr. Tian	600,000	9.09
Yufei Shanshui	315,724	4.78
Zhongcai Qihu	192,308	2.91
Xieyao Kexin	192,308	2.91
Jiaxing Yuhan	165,613	2.51
Ms. Jin Qing	164,968	2.50
Qingdao Bei'an	149,676	2.27
Ruikang Yuhong	84,894	1.29
Hainan Junshi	75,729	1.15
Hemeng Medical Intelligence	60,584	0.92
Qingdao Wangde	54,632	0.83
Suzhou Meilingge	48,077	0.73
Junding Changwang	45,437	0.69
Xieyao Kesheng	45,437	0.69
Fujian Yide	45,437	0.69
Suzhou Industrial Investment	38,588	0.58
Jiuzhou Ketou	38,245	0.58
Fuzhou Xindui	30,292	0.46
Chuangxin Tongxiang	2,775	0.04
Total	6,600,724	100.00

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(l) *Share Transfers in relation to the Employee Incentive Scheme and Capital Increase in January 2025*

As approved by the Shareholders on the January 13, 2025, pursuant to the Employee Incentive Scheme, a series of share transfer agreements were entered into by and between Suzhou Hesheng and each of the transferees (the “**Transferees**”), namely Dr. Shen, Dr. Tian, Dr. Hu Tianwen (胡天文) (executive Director and deputy general manager), Ms. Jin Qing (deputy manager and Ms. Jin Jie’s sister), Dr. Zheng Wei (鄭偉) (assistant to directors of medicinal chemistry department of our Company and supervisor of Qingdao Antai), Dr. Wang Zhiqiang (王志強) (deputy general manager), Ms. Guo Ting (郭婷) (secretary of the Board and joint company secretary), Ms. Yao Zheng (藥箏) (financial controller), Dr. Yang Rulei (楊汝磊) (chairman of the Supervisory Committee) and Mr. Li Jian (李建) (Supervisor), pursuant to which, Suzhou Hesheng agreed to transfer to the relevant Transferee, approximately 5.21%, 0.45%, 0.45%, 1.18%, 0.23%, 0.27%, 0.27%, 0.27%, 0.15% and 0.11% equity interest in our Company, representing 7,818,956 Shares, 681,743 Shares, 681,743 Shares, 1,768,283 Shares, 340,872 Shares, 397,683 Shares, 397,683 Shares, 397,683 Shares, 227,248 Shares and 170,436 Shares respectively upon the completion of the Jan-2025 Capital Increase (as defined below). The consideration for such share transfers was RMB6.00 per Share (prior to the Jan-2025 Capital Increase).

The same date, the Shareholders of our Company, resolved to increase the share capital of our company from RMB6,600,724 to RMB150,000,000 by way of capital increase from capital reserve which represented a registered capital of RMB143,399,276 converted into 143,399,276 Shares, which were subscribed by and issued to the Shareholders of our Company in proportion to their respective equity interest in our Company (the “**Jan-2025 Capital Increase**”).

Upon the completion of the above share transfers in relation to the Employee Incentive Scheme and the Jan-2025 Capital Increase, the shareholding structure of our Company was set forth in the table below:

Shareholders	Number of Shares	Shareholding percentage (%)
Dr. Shen	82,461,110	54.97
Ms. Jin Jie	2,272,478	1.52
Dr. Tian	14,316,611	9.54
Yufei Shanshui	7,174,758	4.78
Suzhou Hesheng	6,783,346	4.52
Ms. Jin Qing	5,517,145	3.68
Zhongcai Qihu	4,370,157	2.91
Xieyao Kexin	4,370,157	2.91
Jiaxing Yuhan	3,763,519	2.51
Qingdao Bei’an	3,401,354	2.27
Ruikang Yuhong	1,929,197	1.29
Hainan Junshi	1,720,925	1.15
Hemeng Medical Intelligence	1,376,758	0.92

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders	Number of Shares	Shareholding percentage (%)
Qingdao Wangde	1,241,500	0.83
Suzhou Meilingge	1,092,539	0.73
Junding Changwang	1,032,546	0.69
Xieyao Kesheng	1,032,546	0.69
Fujian Yide	1,032,546	0.69
Suzhou Industrial Investment	876,904	0.58
Jiuzhou Ketou	869,116	0.58
Fuzhou Xindui	688,379	0.46
Dr. Hu Tianwen	681,743	0.45
Dr. Wang Zhiqiang	397,683	0.27
Ms. Guo Ting	397,683	0.27
Ms. Yao Zheng	397,683	0.27
Dr. Zheng Wei	340,872	0.23
Dr. Yang Rulei	227,248	0.15
Mr. Li Jian	170,436	0.11
Chuangxin Tongxiang	63,061	0.04
Total	150,000,000	100.00

EMPLOYEE INCENTIVE PLATFORM

In recognition of the contributions of our employees and to incentivize them to further promote our development, Suzhou Hesheng was established as our Employee Incentive Platform.

Suzhou Hesheng was established in the PRC as a limited partnership on June 22, 2021 in the PRC. As of the Latest Practicable Date, Mr. Wang Minda (王敏達), a manager of our Company responsible for the overall management of the supply procurement department, is the executive partner of Suzhou Hesheng and is responsible for the management of Suzhou Hesheng. Thus, all management power and voting rights of Suzhou Hesheng reside with Mr. Wang Minda. As of the Latest Practicable Date, Suzhou Hesheng has 46 limited partners, all of whom are existing employees of our Group. The awards under the Employee Incentive Platform has been fully granted.

PRE-[REDACTED] INVESTMENTS

(1) Overview

Between August 2020 and December 2024, we entered into several rounds of Pre-[REDACTED] Investments with the Pre-[REDACTED] Investors through subscriptions for increased registered capital of our Company and/or through transfers by the then Shareholders. For further details, see “— Establishment and Development of Our Company” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(2) Principal terms of the Pre-[REDACTED] Investments

The following table summarizes the key terms of the Pre-[REDACTED] Investments:

	Angel Round Financing ⁽²⁾	Series A Financing ⁽³⁾	Series A+ Financing	Series B Financing ⁽⁴⁾	Series C Financing
Date(s) of agreement(s)	November 2018 January 2019 March 2020 June 2020	September 15, 2021	December 13, 2021 December 14, 2021	April 7, 2022 April 8, 2022 May 6, 2022	April 9, 2024 April 10, 2024 May 7, 2024 September 3, 2024 December 23, 2024
Amount of consideration paid (RMB)	80 million	20 million	50 million	200 million	160 million
Date of payment of full consideration	July 3, 2020	September 29, 2021	December 20, 2021	June 1, 2022	December 23, 2024
Post-money valuation of our Company (RMB) (approximation)	600 million	1,220 million	1,570 million	4,200 million	4,450 million
Cost per Share paid under the Pre-[REDACTED] Investments (RMB) (approximation)	4.62	9.23	11.51	29.32	29.67
Discount to the [REDACTED] ⁽¹⁾ (approximation)	[REDACTED]/%	[REDACTED]/%	[REDACTED]/%	[REDACTED]/%	[REDACTED]/%

Basis of determination of the consideration

The valuation and consideration for each round of the Pre-[REDACTED] Investments were determined based on arm's length negotiations between our Company and the Pre-[REDACTED] Investors after taking into consideration the timing of the investments, the business, operations and status of our business and operating entities, and the prospects of our business.

Lock-up period

Pursuant to the applicable PRC law, all existing Shareholders (including the Pre-[REDACTED] Investors) could not dispose of any of the Shares held by them within 12 months from the [REDACTED].

Use of [REDACTED] from the

Pre-[REDACTED] Investments We utilized the proceeds from the Pre-[REDACTED] Investments for the principal business of our Group, including but not limited to R&D activities, the growth and expansion of our business and general working capital purposes. As of the Latest Practicable Date, approximately 76% of the [REDACTED] from the Pre-[REDACTED] Investments had been utilized.

Strategic benefits to our Group brought by the Pre-[REDACTED] Investors

At the time of the Pre-[REDACTED] Investments, our Directors were of the view that (i) the Pre-[REDACTED] Investments have broadened our shareholder base and demonstrated the Pre-[REDACTED] Investors' confidence in the operation and development of our Group; and (ii) our Group could benefit from the additional funds provided by relevant Pre-[REDACTED] Investors for our research and development and daily operations and the knowledge and experience of the Pre-[REDACTED] Investors.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Notes:

- (1) The discount is based on the indicative price of HK\$[REDACTED] (being the mid-point of the indicative [REDACTED] of as stated in this document) and the indicative exchange rate of HK\$1.00=RMB0.9234.
- (2) On January 19, 2022, Yufei Shanshui entered into an equity transfer agreement with Qizhi Huikang, pursuant to which, Qizhi Huikang agreed to transfer registered capital of our Company of RMB336,538 (representing approximately 5.56% equity interest in our Company at the time) to Yufei Shanshui for a consideration of RMB35 million. The cost per Share of the transfer is RMB4.40 with the post-money valuation of our Company being approximately RMB606 million. Based on the indicative price of HK\$[REDACTED] (being the mid-point of the proposed range of the [REDACTED] as stated in this document) and the indicative exchange rate of HK\$1.00 = RMB0.9234, the discount to the [REDACTED] of the transfer is approximately [REDACTED]%. For details of the transfer, see “— Establishment and Development of our Company — (2) Subsequent Capital Changes and Equity Transfers — (f) Equity Transfer in February 2022” in this section.

Subsequently on May 10, 2024, an equity transfer agreement was entered into by and among Yufei Shanshui, Jiuzhou Ketou and Chuangxin Tongxiang, pursuant to which, Yufei Shanshui agreed to transfer 18,039 Shares and 2,775 Shares of our Company (representing approximately 0.27% and 0.04% equity interest in our Company at the time) to Jiuzhou Ketou and Chuangxin Tongxiang at a consideration of RMB6.5 million and RMB1 million, respectively. The cost per Share of the transfer is RMB15.86 with the post-money valuation of our Company being approximately RMB2,378 million. Based on the indicative price of HK\$[REDACTED] (being the mid-point of the proposed range of the [REDACTED] as stated in this document) and the indicative exchange rate of HK\$1.00 = RMB0.9234, the discount to the [REDACTED] of the transfer is approximately [REDACTED]%. For details of the May-2024 Transfer, see “— Establishment and Development of our Company — (2) Subsequent Capital Changes and Equity Transfers — (i) Share Transfer in May 2024” in this section.
- (3) The post-money valuation of our Company increased after the Angel Round Financing was primarily due to (i) commencement of the R&D for VV116 for the treatment of COVID-19; (ii) commencement for the projects of LV232 and TPN171; and (iii) imminent submission for the end of Phase II (EOPII) conference for TPN171.
- (4) The post-money valuation of our Company increased after the Series A+ Financing was primarily due to (i) imminent completion for GMP compliance inspection for VV116 for the treatment of COVID-19; (ii) acceptance of ANDA application of dapoxetine hydrochloride tablets by CDE; and (iii) approval for VV116 in Uzbekistan.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(3) Rights of the Pre-[REDACTED] Investors

The Pre-[REDACTED] Investors were granted customary special rights, including but not limited to the redemption right, tag-along right, pre-emptive right and anti-dilution right. In accordance with Pre-[REDACTED] Investment Guidance in Chapter 4.2 of the Guide, all these special rights have been terminated prior to the initial filing of the [REDACTED] by our Company with the Stock Exchange (the “[REDACTED]”), provided that such special rights of certain Pre-[REDACTED] Investors shall automatically be reinstated upon occurrence of any one of the following events, among others: (a) the Company withdraws its [REDACTED], (b) the [REDACTED] lapsed and the Company does not renew the [REDACTED] within three months after such lapse; or (c) the [REDACTED] was returned or rejected by relevant authorities and the Company does not apply for review within prescribed time pursuant to relevant rules.

(4) Sole Sponsor’s Confirmation

The Sole Sponsor confirms that the investments by the Pre-[REDACTED] Investors are in compliance with the guidance on pre-[REDACTED] investments in Chapter 4.2 of the Guide.

(5) Information about our Pre-[REDACTED] Investors

Below sets out information of our Pre-[REDACTED] Investors. To the best knowledge of our Directors, save as disclosed in this section, each of our Pre-[REDACTED] Investors and their respective general partner (as applicable) is an Independent Third Party.

Zhongcai Qihu

Zhongcai Qihu is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Zhongcai Qihu is Gongqingcheng Qihu Zhongcai Investment Co., Ltd. (共青城奇虎中財投資有限公司) which in turn is owned as to 40%, 40% and 20% by Zhongcai Financial Holding Investment Co., Ltd. (中財金控投資有限公司) (“**Zhongcai Financial**”), Flying Technology (Beijing) Co., Ltd. (北京奇飛翔藝商務諮詢有限公司) (“**Flying Technology**”) and Tianjin Juxin Land Technology Partnership Enterprise (Limited Partnership) (天津聚信陸號科技合夥企業(有限合夥)), respectively. Zhongcai Financial is ultimately controlled by the State-owned Assets Supervision and Administration Commission of the State Council (國務院國有資產監督管理委員會). Flying Technology has 42 shareholders with its largest shareholder, namely, Tianjin Qixin Technology Co., Ltd. (天津奇信志成科技有限公司), holding approximately 51.78% equity interest. As of the Latest Practicable Date, Zhongcai Qihu has 11 limited partners among which Mr. Sun Lei (孫磊) is the largest limited partner with approximately 15.55% partnership interest.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

**Xieyao Kexin,
Xieyao Kesheng
and Suzhou
Meilingge**

Each of Xieyao Kexin and Xieyao Kesheng is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Xieyao Kexin and Xieyao Kesheng was Suzhou Xieyao Private Fund Management Co., Ltd. (蘇州協耀私募基金管理有限公司) (“**Xieyao PE**”) which is ultimately controlled by Mr. Qiao Gang (喬剛). As of the Latest Practicable Date, Xieyao Kexin has 12 limited partners among which Suzhou Chuangyao Biotechnology Industry Development Co., Ltd. (蘇州創藥生物技術產業發展有限公司) was the largest limited partner with 20% partnership interest. Xieyao Kesheng has 6 limited partners among which Suzhou Institute of Building Science Group Co., Ltd. (蘇州市建築科學研究院集團股份有限公司) (a company listed the Shanghai Stock Exchange (stock code: 603183.SH)) was the largest limited partner with 40% partnership interest.

Suzhou Meilingge is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Suzhou Meilingge is Shen Juan (沈娟). As of the Latest Practicable Date, Suzhou Meilingge has 8 limited partner among which Zhao Hao (趙昊) was the largest limited partner with 40% partnership interest.

Pursuant to an acting-in-concert agreement entered into by and among Xieyao Kexin, Xieyao Kesheng and Suzhou Meilingge, during the term of the agreement, as long as they remain as the Shareholders, (i) Meilingge shall act in concert with Xieyao Kexin and Xieyao Kesheng in exercising its voting power and proposal right as a Shareholder; and (ii) in case of any disagreement between (a) Xieyao Kexin and Xieyao Kesheng, and (b) Suzhou Meilingge, in relation to the exercise of the Shareholders’ voting power and proposal right, Suzhou Meilingge shall follow instructions by Xieyao Kexin and Xieyao Kesheng. As of the Latest Practicable Date, the paid-up registered capital of Xieyao Kexin and Xieyao Kesheng was RMB100 million and RMB150 million. Each of Xieyao Kexin and Xieyao Kesheng is a fund dedicated to the investment in healthcare industry. Apart from the investment in our Company, Xieyao Kexin has invested in certain biotechnology companies, including, Suzhou AlphaMa Biotechnology Co., Ltd. (蘇州阿爾脈生物科技股份有限公司), Wuxi Beita Pharmatech Co., Ltd. (無錫貝塔醫藥科技股份有限公司) and Suzhou Yihua Biological Medicine Technology Co., Ltd. (蘇州頤華生物醫藥技術股份有限公司), etc. and Xieyao Kesheng has invested in Suzhou Haisi Linke Medical Technology Co., Ltd. (蘇州海思臨科醫學科技有限公司). Thus, each of Xieyao Kexin, Xieyao Kesheng and Suzhou Meilingge is a Sophisticated Investor.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- Jiaxing Yuhan** Jiaxing Yuhan is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Jiaxing Yuhan is Hidragon Capital Co., Ltd. (潛龍股權投資管理(上海)有限公司), a company ultimately controlled by Zhang Hanhong (張漢宏). As of the Latest Practicable Date, Jiaxing Yuhan has 10 limited partners among which Beijing Taigote Fund Management Center (Limited Partnership) (北京泰戈特基金管理中心(有限合夥)) is the largest limited partner with approximately 19.87% partnership interest.
- Ruikang Yuhong** Ruikang Yuhong is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Ruikang Yuhong is Shenzhen Xionglue Investment Partnership Enterprise (Limited Partnership) (深圳雄略投資合夥企業(有限合夥)) whose executive partner is Xiong Siyu (熊思宇) with 97% partnership interest. As of the Latest Practicable Date, Ruikang Yuhong has three limited partners among which Shenzhen Ruige Industrial Development Co., Ltd. (深圳市銳革實業發展有限公司), a company controlled by Zhou Zige (周自革), is the largest limited partner with 55% partnership interest.
- Suzhou Industrial Investment** Suzhou Industrial Investment is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, Suzhou Industrial Investment has one executive partner and two limited partners, all of which are ultimately controlled by Suzhou Finance Bureau (蘇州市財政局).
- Yufei Shanshui** Yufei Shanshui is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Yufei Shanshui is Zhongcai Yufei (Beijing) Private Equity Fund Management Co., Ltd. (中財予飛(北京)私募基金管理有限公司). As of the Latest Practicable Date, Yufei Shanshui has 10 limited partners among which Cheng Wenlong (程文龍) is the largest limited partner with approximately 27.55% partnership interest.
- Hainan Junshi** Hainan Junshi is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, Hainan Junshi was owned as to 99.67% by Jin Mingzhe (金明哲).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- Hemeng Medical Intelligence** Hemeng Medical Intelligence is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Hemeng Medical Intelligence is Hangzhou Chaodao Equity Investment Fund Management Co., Ltd. (杭州超道股權投資基金管理有限公司), a company ultimately controlled by Wang Huachun (王華春). As of the Latest Practicable Date, Hemeng Medical Intelligence has 14 limited partners among which Wang Huachun (王華春) was the largest limited partner with approximately 47.33% partnership interest.
- Junding Changwang** Junding Changwang is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Junding Changwang was Junding Private Equity Fund Management Co., Ltd. (君鼎私募基金管理有限公司), a company ultimately owned as to 99% by Zhang Zhongnan (張中楠). As of the Latest Practicable Date, Junding Changwang has 7 limited partners among which Suzhou Junding Kaishan Entrepreneurship Investment Center (Limited Partnership) (蘇州君鼎開山創業投資中心(有限合夥)), ultimately controlled by Zhang Zhongnan (張中楠), was the largest limited partner with 44% partnership interest.
- Fujian Yide** Fujian Yide is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Fujian Yide is Shanghai Hongfu Private Fund Management Co., Ltd. (上海鴻富私募基金管理有限公司) (“**Shanghai Hongfu**”), a company ultimately owned as to 97% by Yang Zhichun (楊志春). As of the Latest Practicable Date, Fujian Yide has 26 limited partners among which Ningbo AUX Investment Management Co., Ltd. (寧波奧克斯投資管理有限公司) was the largest limited partner with approximately 28.14% partnership interest.
- Fuzhou Xindui** Fuzhou Xindui is a limited partnership incorporated in the PRC. As of the Latest Practicable Date, the executive partner of Fuzhou Xindui was Huang Xiankun (黃現琨) with 99% partnership interest.
- Qingdao Bei’an** Qingdao Bei’an is a limited liability company incorporated in the PRC. As of the Latest Practicable Date, it was wholly owned by Qingdao Bei’an Holding Group Co., Ltd. (青島北岸控股集團有限責任公司), a company wholly owned by State owned Assets Development Center of Chengyang District in Qingdao City (青島市城陽區國有資產發展中心).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- Jiuzhou Ketou** Jiuzhou Ketou is a limited liability company incorporated in the PRC. As of the Latest Practice Date, Jiuzhou Ketou has two executive partners, namely, Hubei Jointown Gaotou Changjiang Industrial Investment Fund Management Co., Ltd. (湖北九州通高投長江產業投資基金管理有限公司) (“**Jointown Gaotou**”), a company wholly owned by Jointown Pharmaceutical Group Co., Ltd. (九州通醫藥集團股份有限公司) (“**Jointown Pharmaceutical**”) (a company listed on the Shanghai Stock Exchange (stock code: 600998.SH)), and Hubei Jiuzhou Health Enterprise Management Partnership (Limited Partnership) (湖北九州健康企業管理合夥企業(有限合夥)) whose general partner is Jointown Gaotou. As of the Latest Practice Date, Jiuzhou Ketou has two limited partners, namely, Jointown Pharmaceutical and Wuhan Optics Valley Health Industry Investment Co., Ltd. (武漢光谷健康產業投資有限公司), a company ultimately wholly owned by Management Committee of Wuhan Donghu New Technology Development Zone (武漢東湖新技術開發區管理委員會), with 60.62% and 36.88% partnership interest, respectively.
- Qingdao Wangde** Qingdao Wangde is a limited liability company incorporated in the PRC. As of the Latest Practice Date, the executive partner of Qingdao Wangde was Shanghai Hongfu. As of the Latest Practice Date, Qingdao Wangde has two limited partners, namely, Li Ling (李嶺) and Shi Jing (石靜) with 65.60% and 34.37% partnership interest, respectively.
- Chuangxin Tongxiang** Chuangxin Tongxiang is a limited liability company incorporated in the PRC. As of the Latest Practice Date, the executive partner of Chuangxin Tongxiang is Wang Qin (汪勤). As of the Latest Practice Date, Chuangxin Tongxiang has 7 limited partners among which Wang Yongfei (王庸非) was the largest limited partner with 26% partnership interest.

[REDACTED]

Following the conversion of the [REDACTED] Shares into H Shares and upon completion of the [REDACTED] (assuming that the [REDACTED] is not exercised):

- (a) Dr. Shen (our Controlling Shareholder), Ms. Jin Jie (spouse of Dr. Shen and our Controlling Shareholder), Dr. Tian (chairman of the Board, executive Director, chief executive officer and general manager of our Company), Mr. Hu Tianwen (executive Director and deputy general manager our Company), Ms. Jin Qing (director of Vigonvita Lianyungang and supervisor of Nantong Hefeng), Dr. Zheng Wei (assistant to directors of medicinal chemistry department of our Company and supervisor of Qingdao Antai), Dr. Yang Rulei (chairman of the Supervisory Committee) and Mr. Li Jian (Supervisor) will be our core connected persons and a

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

total of 105,987,643 Shares held by them, representing approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), will not be counted towards the [REDACTED].

- (b) a total of 10,460,435 Unlisted Shares held by Yufei Shanshui, Jiaxing Yuhan, Qingdao Bei'an, Ruikang Yuhong, Fuzhou Xindui, Mr. Wang Zhiqiang, Ms. Guo Ting and Ms. Yao Zheng will not be converted into H Shares and [REDACTED] on the Stock Exchange, and therefore will not be counted as part of the [REDACTED], representing [REDACTED]% of our share capital in aggregate upon [REDACTED] (assuming the [REDACTED] is not exercised);
- (c) a total of 33,551,922 Unlisted Shares held by Yufei Shanshui, Suzhou Hesheng, Zhongcai Qihu, Xieyao Kexin, Jiaxing Yuhan, Ruikang Yuhong, Hainan Junshi, Hemeng Medical Intelligence, Qingdao Wangde, Suzhou Meilingge, Junding Changwang, Xieyao Kesheng, Fujian Yide, Suzhou Industrial Investment, Jiuzhou Ketou, Mr. Wang Zhiqiang, Ms. Guo Ting, Ms. Yao Zheng and Chuangxin Tongxiang (the “**Current Unlisted Shareholders**”) will be converted into H Shares and [REDACTED] on the Stock Exchange, and therefore will be counted as part of the [REDACTED], representing [REDACTED]% of our share capital in aggregate upon [REDACTED] (assuming the [REDACTED] is not exercised). None of the Current [REDACTED] Shareholders is accustomed to take instructions from any core connected persons in relation to the acquisition, disposal, voting or other disposition of their Shares and none of their acquisition of the Shares were financed directly or indirectly by our core connected person; and
- (d) a total of [REDACTED] H Shares issued pursuant to the [REDACTED] will be counted as part of the [REDACTED], representing [REDACTED]% of our share capital in aggregate.

Based on the above, it is expected that immediately following completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), a total of [REDACTED] Shares, representing [REDACTED]% of our total share capital upon the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised) will be counted as part of the [REDACTED]. As a result, over [REDACTED]% of our Company's total issued Shares will be held by the [REDACTED] upon completion of the [REDACTED] as required under Rule 8.08(1)(a) of the Listing Rules. In addition, based on the [REDACTED] of HK\$[REDACTED] per H Share (being the low end of the indicative [REDACTED]), the [REDACTED] of the portion of the total number of the Company's issued Shares held by the [REDACTED] pursuant to the requirements under Rule 18A.07 of the Listing Rules would be over HK\$375 million at the time of the [REDACTED].

Immediately following the completion of the [REDACTED], a total of [REDACTED] Shares, representing [REDACTED]% of our total share capital upon the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), will be subject to a lock-up period. For details, see “— Pre-[REDACTED] Investments — Principal Terms of the Pre-[REDACTED] Investments” above.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CAPITALIZATION OF OUR COMPANY

The table below is a summary of the capitalization of our Company as of the date of this document and the [REDACTED] (assuming the [REDACTED] is not exercised):

Shareholder	As of the date of this document		As of the [REDACTED] (assuming the [REDACTED] is not exercised)					
	Number of Unlisted Shares	Approximate ownership percentage in total issued share capital	Number of H Shares	Approximate ownership percentage in H Shares	Number of Unlisted Shares	Approximate ownership percentage in Unlisted Shares	Total number of Shares	Approximate ownership percentage in total issued share capital
		(%)		(%)		(%)		(%)
Dr. Shen	82,461,110	54.97	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Ms. Jin Jie	2,272,478	1.52	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Tian	14,316,611	9.54	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Yufei Shanshui	7,174,758	4.78	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Suzhou Hesheng	6,783,346	4.52	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Ms. Jin Qing	5,517,145	3.68	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Zhongcai Qihu	4,370,157	2.91	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Xieyao Kexin	4,370,157	2.91	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Jiaxing Yuhan	3,763,519	2.51	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Qingdao Bei'an	3,401,354	2.27	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Ruikang Yuhong	1,929,197	1.29	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Hainan Junshi	1,720,925	1.15	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Hemeng Medical Intelligence	1,376,758	0.92	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Qingdao Wangde	1,241,500	0.83	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Suzhou Meilingge	1,092,539	0.73	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Junding Changwang	1,032,546	0.69	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Xieyao Kesheng	1,032,546	0.69	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Fujian Yide	1,032,546	0.69	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Suzhou Industrial Investment	876,904	0.58	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Jiuzhou Ketou	869,116	0.58	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Fuzhou Xindui	688,379	0.46	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Hu Tianwen	681,743	0.45	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Wang Zhiqiang	397,683	0.27	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Ms. Guo Ting	397,683	0.27	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Ms. Yao Zheng	397,683	0.27	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Zheng Wei	340,872	0.23	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

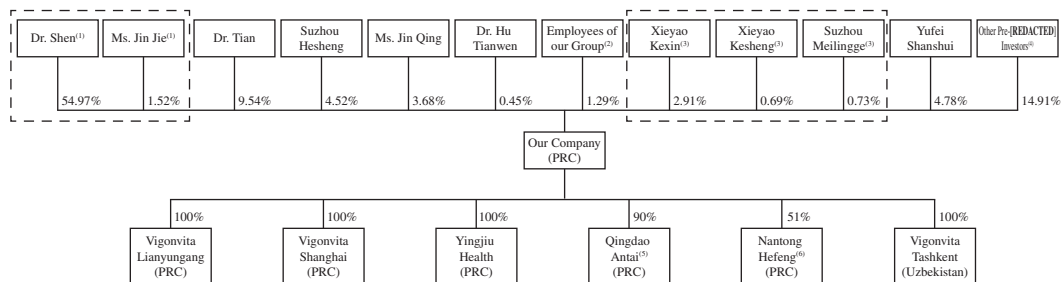
Shareholder	As of the date of this document		As of the [REDACTED] (assuming the [REDACTED] is not exercised)					
	Number of Unlisted Shares	Approximate ownership percentage in total issued share capital (%)	Number of H Shares	Approximate ownership percentage in H Shares (%)	Number of Unlisted Shares	Approximate ownership percentage in Unlisted Shares (%)	Total number of Shares	Approximate ownership percentage in total issued share capital (%)
Dr. Yang Rulei	227,248	0.15	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Mr. Li Jian	170,436	0.11	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Chuangxin Tongxiang	63,061	0.04	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Investors taking parts in the [REDACTED]	-	-	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Total	150,000,000	100.00	[REDACTED]	100.00	[REDACTED]	100.00	[REDACTED]	100.00

CONFIRMATION BY THE PRC LEGAL ADVISORS

Our PRC Legal Advisors have confirmed that the above mentioned equity transfers involving our Shares, increase in share capital and conversion from a limited company to a joint stock company with limited liability have been properly and legally completed in all material respects and all requisite regulatory approvals have been obtained in accordance with the applicable PRC laws and regulations in all material respects.

CORPORATE STRUCTURE IMMEDIATELY BEFORE COMPLETION OF THE [REDACTED]

The chart below sets out the shareholding structure of our Company immediately before completion of the [REDACTED]:



Notes:

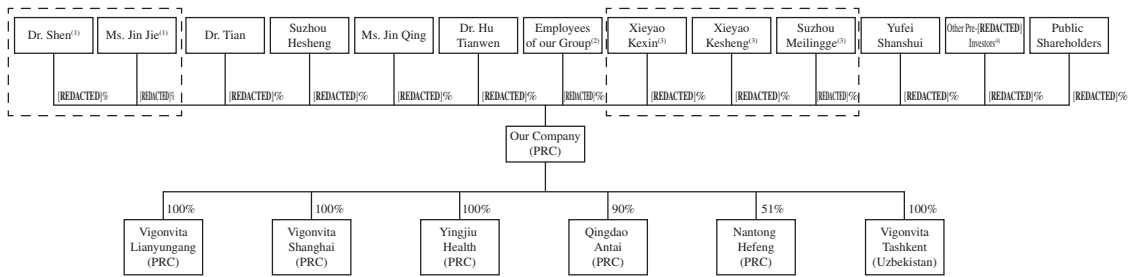
- Ms. Jin Jie is the spouse of Dr. Shen.
- Including: Dr. Wang Zhiqiang, Ms. Guo Ting, Ms. Yao Zheng, Dr. Zheng Wei, Dr. Yang Rulei and Mr. Li Jian. For the details of their shareholding in our Company, see “— Capitalization of our Company” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (3) As of the Latest Practicable Date, the executive partner of Xieyao Kexin and Xieyao Kesheng was Xieyao PE which was ultimately controlled by Mr. Qiao Gang. Pursuant to the acting-in-concert agreement entered into by and among Xieyao Kexin, Xieyao Kesheng and Suzhou Meilingge, during the term of the agreement, as long as they remain as the Shareholders, (i) Meilingge shall act in concert with Xieyao Kexin and Xieyao Kesheng in exercising its voting power and proposal right as a Shareholder; and (ii) in case of any disagreement between (a) Xieyao Kexin and Xieyao Kesheng, and (b) Suzhou Meilingge, in relation to the exercise of the Shareholders’ voting power and proposal right, Suzhou Meilingge shall follow instructions by Xieyao Kexin and Xieyao Kesheng.
- (4) For the details of the background information of the other Pre-[REDACTED] Investors, see “— Pre-[REDACTED] Investments” in this section above.
- (5) As of the Latest Practicable Date, the rest of the 10% equity interest of Qingdao Antai was owned by Shenzhen Hechao Investment Development Co., Ltd. (深圳市合超投資發展有限公司), which is owned as to 90% and 10% by Mr. He Naiyu (何乃愚) and Ms. Fan Jinmei (范金妹), respectively. Save as indirectly holding the equity interest in Qingdao Antai, each of them is an Independent Third Party.
- (6) As of the Latest Practicable Date, the rest of the 49% equity interest of Nantong Hefeng was owned by Mr. Jiang Xiangrui (蔣翔銳). Save as being a substantial shareholder of Nantong Hefeng, Mr. Jiang Xiangrui is an Independent Third Party.

CORPORATE STRUCTURE IMMEDIATELY FOLLOWING COMPLETION OF THE [REDACTED]

The chart below sets out the shareholding structure of our Company immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised):



Notes: For details, see notes (1) and (6) of “— Corporate Structure Immediately Before Completion of the [REDACTED]” in this section above.

BUSINESS

OVERVIEW

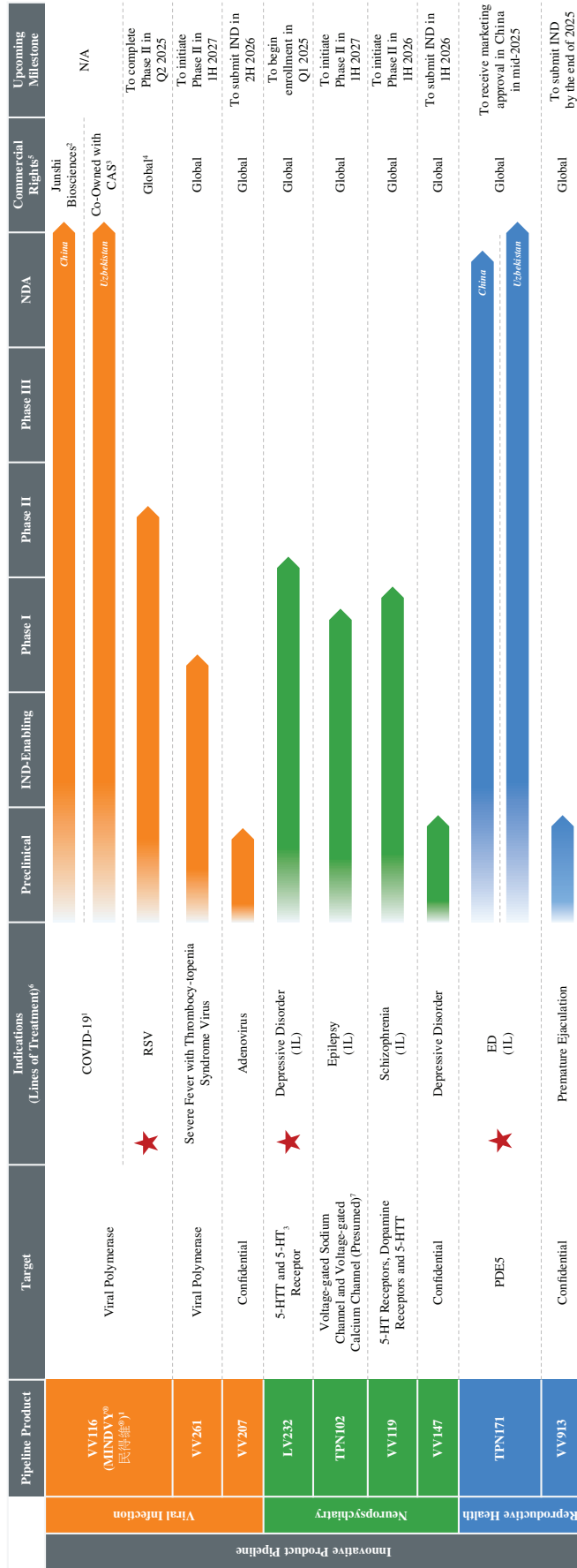
Founded in 2013, we are a fully-integrated biopharmaceutical company dedicated to the discovery, development and commercialization of innovative small molecule drugs. With mission to innovate for better health and quality of life, we strive to address the diverse and evolving patient needs in our strategically focused therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health. Over the past 12 years, we have not only established end-to-end capabilities spanning the entire industry value chain from research and clinical development to manufacturing and commercialization, but also developed a distinguished portfolio of three Core Products each with first- or best-in-class potential.

According to CIC, the three therapeutic areas that we focus on have grown rapidly during the past few years and are expected to continue to expand in the near future. Specifically, the antiviral drug market, neuropsychiatric drug market and reproductive health drug market in China are forecasted to increase from RMB24.9 billion, RMB107.5 billion and RMB34.2 billion in 2023, respectively, to RMB44.9 billion, RMB137.5 billion and RMB39.8 billion in 2035, respectively, with a CAGR of 5.0%, 2.1% and 1.3%, respectively. Despite the significant growth, there still exist considerable challenges in developing successful therapies in these therapeutic areas, presenting huge unmet clinical needs and substantial market opportunities for innovative treatments. For example, viral diseases are one of the major threats to human health and the ongoing emergence of new viruses and variants has underscored urgent needs for more adaptable broad-spectrum therapies. We have demonstrated our capability and commitment to effectively and rapidly respond to evolving and unanticipated public health emergencies caused by viral diseases.

We are one of the few fully-integrated biopharmaceutical companies in China. The full integration allows us to bring our drug candidates efficiently and cost-effectively from bench to bedside, and it also enables us to identify and address urgent and significant unmet clinical needs. As of the Latest Practicable Date, we had built a highly competitive and differentiated pipeline of nine innovative assets, including two in commercial or near-commercial stage, four in clinical stage and three in preclinical stage. In addition to our innovative pipeline, we have established a generic portfolio, including three drugs in commercial or near-commercial stage. We believe that our assets in commercial or near-commercial stage provide us with first-mover advantages in advancing our brand name and market position in the relevant therapeutic areas. They also provide visible and recurring revenue streams and cash flows, thereby enhancing our overall resilience. Such a de-risked pipeline allows us to effectively manage the development risks and timing of our investment in R&D.

BUSINESS

The following chart shows our pipeline of innovative assets as of the Latest Practicable Date:



★ Core Products

BUSINESS

Abbreviations: 1L = first-line; N/A = not applicable; 5-HTT = serotonin transporter; 5-HT₃ = 5-hydroxytryptamine 3; PDE = phosphodiesterase; CDE = Centre for Drug Evaluation; IND = investigational new drug application; RSV = respiratory syncytial virus; ED = erectile dysfunction; Q2 = second quarter; 1H = first half; 2H = second half; mid-2025 = second to third quarter of 2025.

Notes:

1. VV116 received conditional marketing approval in China for the treatment of COVID-19 under the trade name 民得維® in January 2023, and received full approval in January 2025, and secured marketing approval in Uzbekistan for the treatment of moderate and severe COVID-19 under the trade name MINDVY® in December 2021.
2. We co-discovered VV116 in collaboration with Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS. We acquired exclusive global intellectual property rights related to VV116 from Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS. For details, see “— Collaboration Arrangement — VV116 Agreements.” Starting in September 2021, we entered into a series of agreements with Junshi Biosciences, granting exclusive global rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19, with the exception of five countries in Central Asia (Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan), and Russia. For details, see “— Collaboration Arrangement — VV116 Agreements.”
3. Under a co-development agreement, we jointly own the rights to research, develop, manufacture, and commercialize VV116 for COVID-19 treatment with the Xinjiang Technical Institute of Physics and Chemistry, CAS in five Central Asian countries (Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan). For details, see “— Collaboration Arrangement — VV116 Agreements.”
4. We were heavily involved in the development of VV116 for the treatment of COVID-19 and are currently conducting clinical development for the treatment of RSV infection in China.
5. We hold exclusive global rights to research, develop, manufacture, and commercialize TPN171, LV232, VV261, TPN102, VV119, and VV913. We discovered and are internally developing VV119. For TPN171 and LV232, our founder Dr. Tian has made significant contributions to their discovery while he was working at Topharman Shanghai. We acquired exclusive global intellectual property rights related to TPN171 from Shanghai Institute of Materia Medica, CAS, Topharman Shanghai, and Shandong Topharman and acquired exclusive global intellectual property rights related to LV232 from Shanghai Institute of Materia Medica, CAS, and Topharman Shanghai. For details, see “— Collaboration Arrangement.” For VV261, TPN102, and VV913, we co-discovered these products with Topharman Shanghai and/or Independent Third Party partners, and subsequently acquired exclusive global rights. Regarding VV207 and VV147, we co-discovered these candidates with Independent Third Party partners and jointly own the global rights to research, develop, manufacture, and commercialize them.
6. Except for depressive disorder, epilepsy, schizophrenia and ED, currently there are no guidelines with respect to the treatment lines of the other indications targeted by our pipeline products, according to CIC.
7. According to preclinical studies, TPN102 demonstrated inhibitory activity on two ion channel receptors — sodium and calcium channels — at micromolar levels *in vivo*. Furthermore, TPN102 exhibited significant antiepileptic effects in various animal models of epilepsy, suggesting that both sodium and calcium channels may be the potential targets for TPN102. Based on data observed in these preclinical studies, as of the Latest Practicable Date, we believed that TPN102 targeted sodium and calcium channels.

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Our Core Products have demonstrated outstanding therapeutic efficacy and extensive indication expansion opportunities, which underscore their significant market potential to address huge clinical needs. Below is an introduction of our Core Products:

- **VV116.** VV116 is a RdRp inhibitor which has been approved for the treatment of COVID-19 in China and Uzbekistan under the trade names 民得維[®] and MINDVY[®], respectively, and is currently under Phase II/III clinical development for the treatment of RSV infection in China. RdRp, an enzyme that catalyzes the replication of RNA from an RNA template and highly conserved in various known RNA viruses, is a promising target for antiviral drugs with better adaptability to emerging variants.

The robust therapeutic efficacy of VV116 for COVID-19 treatment was well evidenced by its Phase III clinical results, which were published in influential journals, including The New England Journal of Medicine and The Lancet Infectious Diseases. In particular, data showed that VV116 was noninferior to Paxlovid in reducing the time to sustained clinical symptom resolution among patients with mild-to-moderate COVID-19 at risk for progression with improved safety profile.

As of the Latest Practicable Date, we were conducting a Phase II/III clinical trial of VV116 dry suspension in RSV-infected infants and young children aged one to 24 months. RSV is a RNA virus that could pose a persistent threat to children, the elderly and immunocompromised population. There were 25.5 million RSV infection cases in China and 136.2 million globally in 2023, according to CIC. However, there is no innovative small molecule antiviral drug approved for RSV infection globally. As of the Latest Practicable Date, VV116 was the only clinical-stage drug candidate for the treatment of RSV infection targeting RdRp in China.

Preclinical studies have demonstrated that VV116 exhibits inhibitory activity against the original SARS-CoV-2 strain and various known variants, including Alpha, Delta and Omicron, as well as other RNA viruses, including Zika virus and Ebola virus. These findings suggest that the clinical application of VV116 could be significantly expanded to address challenging and high-risk viral infection, potentially including the treatment of co-infections involving multiple RNA viruses. Also, the synergistic effects of VV116 when combined with other antiviral drugs, such as nirmatrelvir, a 3C-like protease inhibitor, has been preliminarily validated in preclinical studies, indicating its potential to serve as a backbone drug in the antiviral therapeutic area.

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- **LV232.** LV232 is a potential first-in-class dual-target 5-HTT/5-HT₃ receptor modulator. With a unique mechanism of action, the two targets of LV232 work synergistically, enhancing the antidepressant effects while reducing the severity of common gastrointestinal side effects, such as nausea and vomiting. We plan to initiate a Phase II clinical trial of LV232 for the treatment of depressive disorder in China in the first quarter of 2025.

According to GBD2021, in China, the number of depressive disorder patients increased from 48.2 million in 2018 to 50.4 million in 2023, and is expected to further grow to 53.1 million in 2035. The global prevalence of depressive disorder patients increased from 303.7 million in 2018 to 355.3 million in 2023, and is expected to further grow to 399.4 million in 2035, according to CIC. These patients face significant unmet clinical needs — according to CIC, for up to 40% of patients, standard treatment of antidepressants are not effective.

Compared to currently marketed antidepressants, LV232 is expected to reduce gastrointestinal side effects and potentially improve patient compliance. In more than 100 healthy subjects in the completed Phase I clinical trials of LV232, all adverse reactions were in Grade 1 severity and fully reversible. Given its high safety profile and patient adherence, LV232 is expected to have an extremely low discontinuation rate, which could significantly improve its effectiveness in treating depression. In addition, according to preclinical studies in various depression animal models, LV232 demonstrated significant antidepressant effects at lower doses compared to positive control, an antidepressant that selectively blocks serotonin reuptake. Additionally, LV232 exhibited preliminary efficacy in animal models of anxiety and pain.

- **TPN171.** TPN171 is a potential best-in-class, highly potent and highly selective PDE5 inhibitor, which has been approved for the treatment of ED in Uzbekistan. We filed an NDA for TPN171 for the treatment of ED in China in September 2023, and we anticipate to obtain NDA approval around mid-2025.

According to CIC, PDE5 inhibitors are the standard first-line treatment for ED with the global PDE5 inhibitor market reaching US\$10.0 billion in 2023. The PDE5 inhibitor market in China grew rapidly from RMB5.5 billion in 2018 to RMB9.3 billion in 2023, representing a CAGR of 11.2%, and is expected to continue to increase significantly with a CAGR of 4.2% to reach RMB15.2 billion in 2035. Despite the enormous market demands, the currently approved PDE5 inhibitors exhibit strong inhibitory activity on other PDE isozymes, leading to adverse events that may negatively affect patient compliance and cause safety concerns.

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TPN171 has demonstrated impressive efficacy and safety profiles in its clinical trials. Based on the results from our Phase III clinical trial, TPN171 improved erection function significantly in all dosage groups (2.5 mg/5 mg/10 mg) with the lowest dosage being 2 to 80 times lower than those of comparable PDE5 inhibitors. As a non-head-to-head comparison, such results showed TPN171 potentially demonstrated better efficacy at a lower dose compared to marketed PDE5 inhibitors in China. In addition, based on a non-head-to-head comparison, data collected from a Phase III clinical trial in all TPN171 dose groups showed that the incidence of headache, flushing and gastrointestinal adverse events was lower than that observed with comparable PDE5 inhibitors, with no occurrence of common adverse reactions such as back pain, myalgia or visual abnormalities. This suggests that TPN171 may offer improved safety profile and thus enhanced patient adherence.

TPN171 offers superior patient compliance with an onset time of as short as half an hour. Meanwhile, with a half-life of 8 to 11 hours, TPN171 is expected to have a relatively long duration of action. Also, Phase I clinical trial results showed that certain special populations did not require dosage adjustments and TPN171 absorption was not affected by a standard meal, a high-fat diet or moderate amount of alcohol consumption.

We have established robust in-house R&D capabilities that encompasses all key functionalities throughout the entire drug development process, including hit discovery, lead optimization, druggability evaluation and PCC identification, preclinical research, CMC development, clinical study and regulatory affairs. Our in-house R&D capabilities are bolstered by advanced R&D infrastructure and our proprietary technology platforms. Our R&D centers are located in Suzhou and Shanghai with an aggregate GFA of over 8,000 sq.m. Our R&D team has profound industry, academic and research experience and also plays a vital role in building and advancing our pipeline. As of September 30, 2024, we had a dedicated in-house R&D team of 148 employees with an average of more than 10 years of industry experience and more than 50% of our R&D team members held master’s or above degrees. Complementing our R&D infrastructure, we have established proprietary technology platforms focused on (i) rapid discovery of innovative therapeutic compounds, and (ii) investigation and optimization of the discovered compounds. We believe our technology platforms enable us to identify and address potential clinical and manufacturing issues early in the development process so we can direct our efforts towards compounds with the best potential to become clinically active, cost-effective and commercially viable drugs.

Our fully-integrated capabilities are also reflected in our established manufacturing and commercial capabilities. We have established a GMP-standard commercial-scale in-house manufacturing facility located in Lianyungang, Jiangsu Province, with an aggregate GFA of approximately 51,955 sq.m. and an annual designed manufacturing capacity of 100 million capsules and 600 million tablets. We believe that our in-house manufacturing capability enhances the efficiency of our development and manufacturing processes, allowing us to achieve reliable quality and cost control and ensure stable and timely clinical and commercial drug supply to weather any supply chain disruptions. We have established a dedicated business

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development and commercialization team of 14 employees with an average of more than 13 years of industry experience as of September 30, 2024. We believe that our in-house commercial capabilities will provide strong support for the upcoming commercialization of our drug candidates. Moreover, we foster an open and collaborative mindset and proactively pursue licensing and collaboration arrangements with leading industry players to maximize the clinical and commercial value of our assets.

We are led by our visionary and seasoned founders and management team. Dr. Shen, one of our founders, is a renowned scientist in development of small molecule drugs with more than 30 years of industry experience. Dr. Shen is a researcher, group leader, and doctoral supervisor at the Shanghai Institute of Materia Medica, CAS. He has been selected as a “State Council Special Allowance Expert (國務院特殊津貼專家)” by the State Council and been appointed as a honorary professor of Samarkand State University. He has received the “Excellent Supervisor Award of the CAS (中國科學院優秀導師).” In addition, Dr. Shen was awarded the “Most Beautiful Scientific and Technological Worker in Shanghai (上海市最美科技工作者)” by six governmental departments in Shanghai. Dr. Tian, our founder, chairman of the Board, executive Director, chief executive officer and general manager of our Company, has more than 20 years of industry experience. Dr. Tian led or participated in a number of national scientific research projects, such as Major Science and Technology Special Project for “Significant New Drugs Development” (“重大新藥創制”科技重大專項) and the National High-tech R&D Program (“863 Program”). We believe that the experience and expertise of our management team will continue to drive our future growth.

OUR COMPETITIVE STRENGTHS

Fully-integrated biopharmaceutical company with a highly competitive and differentiated pipeline of innovative assets to capture substantial market opportunities in three strategically focused therapeutic areas

We are one of the few fully-integrated biopharmaceutical companies in China with end-to-end capabilities spanning the entire industry value chain, from research and clinical development to manufacturing and commercialization. The full integration allows us to bring our drug candidates efficiently and cost-effectively from bench to bedside, and it also enables us to identify and address urgent and significant unmet clinical needs.

Leveraging our end-to-end capabilities, especially our robust in-house R&D capabilities empowered by proprietary technology platforms, we have built a highly competitive and differentiated pipeline of innovative assets and will continue to expand its depth and breadth. Our pipeline comprises a mix of assets in commercial, near-commercial, clinical and preclinical stage. Such a de-risked pipeline allows us to effectively manage the development risks and timing of our investment in R&D.

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We take a systematic, patient- and indication-oriented approach to target prevalent or hard-to-treat diseases closely relating to the quality of life, and other diseases and conditions affecting a large and underserved population. Guided by this approach, we have strategically selected and focused on three therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health. There exist considerable challenges in developing successful therapies in these therapeutic areas and overcoming the limitations in current therapies will not only advance therapeutic innovation, but may also unlock substantial market opportunities. We believe that we are well positioned to capitalize on the potential of our pipeline assets and capture market shares in our strategically focused therapeutic areas.

- ***Viral infection.*** Viral diseases are one of the major threats to human health and have imposed a substantial burden on the global economy. In recent years, climate change and globalization have accelerated the spread of viruses. Since the establishment of the Public Health Emergency of International Concern pursuant to the International Health Regulations in 2005, the WHO has declared seven virus outbreak-related international public health emergencies and issued warnings about the potential for more severe global pandemics caused by viral infection in the future. The prevention and control of viral diseases has become a key focus in the global healthcare industry. However, for many viral diseases with significant public health burdens, there are a limited number of, and in some cases, no available vaccines or antiviral drugs, resulting in significant unmet need. Meanwhile, the ongoing emergence of new viruses and variants has underscored urgent needs for more adaptable broad-spectrum therapies.

According to CIC, the antiviral drug market in China increased from RMB22.2 billion in 2018 to RMB24.9 billion in 2023, representing a CAGR of 2.3%. It is expected that the antiviral drug market in China will grow at a CAGR of 5.0% from 2023 to 2035, reaching RMB44.9 billion in 2035. The global antiviral drug market increased from US\$67.7 billion in 2018 to US\$94.2 billion in 2023, representing a CAGR of 6.8%, and is expected to continue to increase to US\$97.4 billion in 2035.

We have demonstrated our capability and commitment to effectively and rapidly respond to evolving and unanticipated public health emergencies. Leveraging our deep expertise and insights in nucleoside-based drugs, we are developing three antiviral drug candidates including VV116, VV261 and VV207. VV116, a Core Product, has been approved for the treatment of COVID-19 infection in both China and Uzbekistan. We are currently conducting a Phase II/III clinical trial of VV116 in RSV infection in China, and we anticipate to complete the ongoing Phase II clinical stage of this trial in the second quarter of 2025. We are also developing VV261 for the treatment of SFTSV infection. VV261 is currently in the Phase I clinical stage. VV207 is currently in preclinical studies for the treatment of adenovirus infection.

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- ***Neuropsychiatry.*** Neuropsychiatric disorders represent a critical healthcare challenge due to their widespread prevalence and significant impact on quality of life. Neuropsychiatric disorders currently affect billions of people globally. According to CIC, in 2023, there were 239.6 million neuropsychiatric disorder patients in China, including 50.4 million depressive disorder patients, 10.3 million epilepsy patients and 15.2 million schizophrenia patients, and the neuropsychiatric drug market in China reached RMB107.5 billion in the same year. The global neuropsychiatric drug market increased from US\$164.2 billion in 2018 to US\$198.5 billion in 2023, representing a CAGR of 3.9%, and is expected to continue to increase to US\$254.0 billion in 2035, representing a CAGR of 2.1% from 2023 to 2035.

While the incidence of these disorders is on an upward trajectory, primarily driven by aging population, improved diagnostic capabilities, growing public awareness and gradual reduction in the social stigma, many neuropsychiatric disorders are still under-diagnosed and under-treated. For example, the depression detection rate for adults in China was 10.6%, compared to a diagnosis rate of 18.4% in the U.S., according to CIC, indicating enormous growth potential. However, traditional antidepressants are often associated with delayed onset of efficacy, suboptimal symptom control and significant systemic side effects. Meanwhile, the complexity and heterogeneity of pathophysiological mechanisms, difficulties in drug delivery across the BBB, and the often chronic nature of neuropsychiatric disorders contribute to the challenges in developing successful therapies to address the root causes of these disorders. The lack of effective treatment options underscores the urgent need for innovation.

We are developing four drug candidates in neuropsychiatry. LV232, a Core Product, has completed its Phase I clinical trial and we plan to commence a Phase II clinical trial for the treatment of depressive disorder in China in the first quarter of 2025. We are also developing VV119 and TPN102 for the treatment of schizophrenia and epilepsy, respectively. Both VV119 and TPN102 are currently in the Phase I clinical stage. VV147, which is currently in preclinical studies, is designed to provide rapid therapeutic effects for the treatment of depressive disorder.

- ***Reproductive Health.*** Reproductive health diseases include a variety of conditions that affect the male and female reproductive systems and their functions. According to CIC, the reproductive health drug market in China grew from RMB29.4 billion in 2018 to RMB34.2 billion in 2023, representing a CAGR of 3.0%, and is expected to continue to grow to RMB39.8 billion in 2035. The global reproductive health drug market reached US\$78.2 billion in 2023.

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We are developing two drug candidates in reproduction health. TPN171, a Core Product, has been approved for the treatment of ED in Uzbekistan. We filed an NDA for TPN171 for the treatment of ED in China in September 2023, and we anticipate to obtain NDA approval around mid-2025. We are also developing VV913 for the treatment of PE. VV913 is currently in preclinical studies and we plan to submit IND application to the NMPA in by the end of 2025.

Three Core Products with first- or best-in-class potential, outstanding therapeutic efficacy and extensive indication expansion opportunities

We have developed three Core Products each with first- or best-in-class potential. Our Core Products have demonstrated outstanding therapeutic efficacy and extensive indication expansion opportunities, which underscore their significant market potential to address huge clinical needs.

- **VV116.** VV116 is a RdRp inhibitor which has been approved for the treatment of COVID-19 in China and Uzbekistan under the trade names 民得維® and MINDVY®, respectively, also known as deuremidevir hydrobromide tablets, and is currently under Phase II/III clinical development for the treatment of RSV infection in China. RdRp is an enzyme that catalyzes the replication of RNA from an RNA template and is highly conserved in various known RNA viruses, including COVID-19 and RSV. By disrupting RdRp function, new RNAs cannot be replicated from an RNA template strand, thereby disrupting the replication of RNA viruses. RdRp is essential for the replication of RNA viruses and is highly conserved, which makes it a promising target for antiviral drugs with better adaptability to emerging variants.

Leveraging our formulation development platforms, we have developed a new dry suspension formulation of VV116. In May 2023, we received IND approval from the NMPA to conduct a Phase I clinical trials of VV116 in dry suspension formulations. As of the Latest Practicable Date, we were conducting a Phase II/III clinical trial of VV116 for the treatment of hospitalized infants and young children aged one to 24 months infected with RSV in China. Our clinical development strategy focuses on pursuing fast market entry while exploring extensive opportunities for expanding indications and patient populations after receiving marketing approval.

RSV is a RNA virus that could pose a persistent threat to children, the elderly and immunocompromised population. There were 25.5 million RSV infection cases in China and 136.2 million globally in 2023, according to CIC. In particular, infants and young children aged one to 24 months account for approximately 30.6% and 38.3% of the RSV patient population in China and globally. However, there is no innovative small molecule antiviral drug approved for RSV infection globally. With supportive care remaining the current clinical standard for RSV infection, the development of effective RSV treatment represents a huge unmet medical need worldwide. As of the Latest Practicable Date, VV116 was the only clinical-stage drug candidate for the treatment of RSV infection targeting RdRp in China.

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Highlights of VV116 include:

- Favorable safety and efficacy profile for COVID-19 treatment: As a drug approved for marketing in both China and Uzbekistan, preclinical and clinical studies have shown that VV116 has substantial antiviral effects against the original and mutant strains of COVID-19, without causing genotoxicity. The encouraging results of its Phase III clinical trials were published in influential journals, including The New England Journal of Medicine and The Lancet Infectious Diseases. In particular, data showed that VV116 was noninferior to Paxlovid in reducing the time to sustained clinical symptom resolution among patients with mild-to-moderate COVID-19 at risk for progression with improved safety profile. Moreover, three Phase I studies among healthy individuals revealed satisfactory safety and pharmacokinetic profiles for VV116.
- Promising therapeutic effect for the treatment of RSV: Preclinical studies have shown that VV116 exhibits strong *in vitro* inhibitory activity against RSV and demonstrates significant efficacy in animal models of RSV infection. In the human bronchial epithelial cells, the EC₅₀ of VV116 against RSV can reach approximately 90 nM. In the Balb/c mouse model, VV116 at doses of 25, 50, and 100 mg/kg significantly reduced the viral RNA copy numbers and viral titers in the lungs of mice. At a dose of 50 mg/kg, VV116 was able to reduce the viral titer to below the detection limit and showed significant improvement in the pathological changes of the lungs.

In a completed Phase I clinical study conducted in healthy adult individuals in China, data demonstrated that administration of VV116 dry suspension with infant formula did not affect the bioavailability of VV116. The trial also confirmed VV116's favorable safety profile, with all adverse drug reactions being Grade ≤ 2 in severity and no serious adverse events or Grade ≥ 3 adverse events reported. Furthermore, the incidence of adverse drug reactions showed no clear dose-dependent trend, underscoring its overall safety.

- Potential as a broad-spectrum antiviral drug: Given that VV116 targets the highly conserved active site of RdRp, it is expected to exhibit the same level of inhibitory activity against future SARS-CoV-2 variants. Preclinical studies have demonstrated that VV116 possesses significant inhibitory activity against the original SARS-CoV-2 strain, various known variants, including Alpha, Delta and Omicron as well as other coronaviruses, such as OC43 and 229E. In addition to its activity against coronaviruses, *in vitro* studies have shown that VV116 also inhibits other RNA viruses, including Zika virus and Ebola virus. These findings suggest that the clinical application of VV116 could be significantly expanded to address challenging and high-risk viral infection, potentially including the treatment of co-infections involving multiple RNA viruses.

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- Potential as a backbone drug combined with other anti-RNA virus therapies:
In preclinical studies, VV116 has demonstrated synergistic effects with other antiviral drugs, such as nirmatrelvir, a 3C-like protease inhibitor, indicating its potential to serve as a backbone drug in the antiviral therapeutic area.
- **LV232.** LV232 is a potential first-in-class dual-target 5-HTT/5-HT₃ receptor modulator. With a unique mechanism of action, the two targets of LV232 work synergistically, enhancing the antidepressant effects while reducing the severity of common gastrointestinal side effects, such as nausea and vomiting. We plan to initiate a Phase II clinical trial of LV232 for the treatment of depressive disorder in China in the first quarter of 2025.

Depressive disorder is one of the most common mental disorders, characterized primarily by a significant and persistent low mood, accompanied by varying degrees of cognitive and behavioral changes. According to GBD2021, in China, the number of depressive disorder patients increased from 48.2 million in 2018 to 50.4 million in 2023, and is expected to further grow to 53.1 million in 2035. The global prevalence of depressive disorder patients increased from 303.7 million in 2018 to 355.3 million in 2023, and is expected to further grow to 399.4 million in 2035, according to CIC. These patients face significant unmet clinical needs — according to CIC, for up to 40% of patients, standard treatment of antidepressants are not effective. Also, it usually takes quite a few days for depressive disorder patients to recognize the therapeutic responses to antidepressants while side effects may occur in a shorter period of time. The slow-onset of antidepressant effects and relatively faster occurrence of side effects may temporally worsen symptoms, bringing extra physical and psychological burdens to the patients. As of the Latest Practicable Date, on a global scale, LV232 was the only innovative small molecule antidepressant exclusively targeting both the 5-HTT and 5-HT₃ receptor.

Highlights of LV232 include:

- Improved BBB permeability: LV232 has strong BBB penetration capability. Preclinical studies of drug distribution in animal tissue indicated that LV232 has excellent BBB permeability. An *in vivo* study in cynomolgus monkeys showed the average concentration of LV232 in the brain was significantly higher than in the plasma, with a brain-to-plasma ratio of approximately 15.

Additionally, pharmacokinetic studies from our Phase I clinical trial showed that LV232 and its metabolites reached steady state after two to three days of continuous administration. Positron emission tomography studies also revealed that a single oral dose of LV232 achieved over 80% occupancy of the 5-HTT receptor in the brain of healthy subjects.

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- Improved safety profile: Compared to currently marketed antidepressants, LV232 is expected to reduce the severity of common gastrointestinal side effects such as nausea and vomiting, and potentially improve patient compliance. In more than 100 healthy subjects in the completed Phase I clinical trials of LV232, all adverse reactions were in Grade 1 severity and fully reversible. Given its high safety profile, LV232 is expected to have an extremely low discontinuation rate, which could significantly improve its effectiveness in treating depression.
- Encouraging efficacy profile based on preclinical studies: According to preclinical studies in various depression animal models, LV232 demonstrated significant antidepressant effects at lower doses compared to positive control, an antidepressant that selectively blocks serotonin reuptake. Additionally, LV232 exhibited preliminary efficacy in animal models of anxiety and pain.
- **TPN171**. TPN171 is a potential best-in-class, highly potent and highly selective PDE5 inhibitor. PDE5 is primarily found in smooth muscle, and inhibiting PDE5 prevents the degradation of cyclic guanosine monophosphate, thereby increasing its concentration, promoting smooth muscle relaxation, arterial dilation and blood filling, which enhances penile erection. TPN171 has been approved for the treatment of ED in Uzbekistan. We filed an NDA for TPN171 for the treatment of ED in China in September 2023, and we anticipate to obtain NDA approval around mid-2025.

According to CIC, PDE5 inhibitors are the standard first-line treatment for ED with the global PDE5 inhibitor market reaching US\$10.0 billion in 2023. The PDE5 inhibitor market in China grew rapidly from RMB5.5 billion in 2018 to RMB9.3 billion in 2023, representing a CAGR of 11.2%, and is expected to continue to increase significantly with a CAGR of 4.2% to reach RMB15.2 billion in 2035. Despite the enormous market demands, the currently approved PDE5 inhibitors — while sharing the same mechanism of action — exhibit strong inhibitory activity on other PDE isozymes such as PDE1, PDE6 and PDE11, leading to adverse events that may negatively affect patient compliance and cause safety concerns. This highlights a significant opportunity for the development of new PDE5 inhibitors with improved safety profiles to better meet patient needs.

Highlights of TPN171 include:

- High selectivity against PDE5: TPN171 is a highly selective PDE5 inhibitor with a novel chemical structure. TPN171 has exhibited significantly higher selectivity over PDE1 and PDE6 compared to sildenafil and for PDE11 compared to tadalafil, implying that fewer side effects from the treatment with TPN171 can be anticipated.

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- High potency with potentially better efficacy: The efficacy of pharmacological agents, including PDE5 inhibitors, in treating ED has traditionally been assessed using patient diaries and questionnaires. We evaluated the therapeutic effect of TPN171 for ED treatment based on improvements in erectile function (IIEF-EF), successful penile insertion rate (SEP2), and successful erection maintenance rate (SEP3). The results from our Phase III clinical trial demonstrated that TPN171 improved all three indicators in all dosage groups (2.5 mg/5 mg/10 mg) showing outstanding efficacy profile. Specifically, in the Phase III clinical trial, compared to the placebo group, all treatment groups exhibited at least a 2.7-point ($P < 0.001$) improvement in the change from baseline in IIEF-EF scores, at least an 8.53% ($P < 0.001$) increase in the percentage of “Yes” responses for SEP2, and at least a 15.21% ($P < 0.001$) increase in the percentage of “Yes” responses for SEP3, significantly outperforming the placebo group.

We also observed that a 2.5 mg dose of TPN171 achieved better erection functional scores of all these three indicators, compared to comparable PDE5 inhibitors with doses ranging from 2 to 80 times higher than that of TPN171. As a non-head-to-head comparison, such results showed TPN171 potentially demonstrated better efficacy at a lower dose compared to marketed PDE5 inhibitors in China.

- Favorable safety profile: Based on a non-head-to-head comparison, data collected from a Phase III clinical trial in all TPN171 dose groups (2.5, 5, and 10 mg) showed that the incidence of headache, flushing and gastrointestinal adverse events was lower than that observed with comparable PDE5 inhibitors, with no occurrence of common adverse reactions such as back pain, myalgia or visual abnormalities. This suggests that TPN171 may offer improved safety profile and thus enhanced patient adherence.
- Improved patient compliance: TPN171 has demonstrated rapid absorption and onset. Phase I clinical trial results showed that the t_{max} ranged from 0.5 to 1.3 hours, indicating an onset time as short as half an hour. Meanwhile, with a half-life of 8 to 11 hours, TPN171 is expected to have a relatively long duration of action.

Phase I clinical trial results in special populations showed that elderlies, as well as those with mild to moderate liver impairment or mild to severe renal impairment, did not require dosage adjustments. Also, according to Phase I clinical trial results, TPN171 absorption was not affected by a standard meal or a high-fat diet. In addition, when taken with moderate amount of alcohol, the pharmacokinetic behavior and safety profile of TPN171 were not affected.

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Robust in-house R&D capabilities empowered by proprietary technology platforms, fueling continuous innovation

We have established robust in-house R&D capabilities that encompasses all key functionalities throughout the entire drug development process, including hit discovery, lead optimization, druggability evaluation and PCC identification, preclinical research, CMC development, clinical study and regulatory affairs. As a validation of our robust R&D capabilities, we have established a proven track record in successfully advancing scientific discoveries into clinical applications. Our in-house R&D capabilities are bolstered by advanced R&D infrastructure and our proprietary technology platforms. These resources serve as the foundation for the successful development and commercialization of our existing drug candidates, while empowering continuous pipeline expansion.

Our R&D centers, located in Suzhou and Shanghai with an aggregate GFA of over 8,000 sq.m., are equipped with advanced laboratories and state-of-art equipment and instruments. Our strong R&D team, led by Dr. Tian, our founder, chairman of the Board, executive Director, chief executive officer and general manager of our Company, has profound industry, academic and research experience and also plays a vital role in building and advancing our pipeline. As of September 30, 2024, we had a dedicated in-house R&D team of 148 employees with an average of more than 10 years of industry experience and more than 50% of our R&D team members held master's or above degrees.

Our proprietary technology platforms focus on (i) rapid discovery of innovative therapeutic compounds, and (ii) investigation and optimization of the discovered compounds. We believe our technology platforms enable us to identify and address potential clinical and manufacturing issues early in the development process so we can direct our efforts towards compounds with the best potential to become clinically active, cost-effective and commercially viable drugs. Highlights of our proprietary technology platforms include:

- ***Innovative drug discovery platform for viral infection:*** With the aim to promptly address currently identified viral infection and future potential viral outbreaks with significant public health burdens, we have developed an innovative drug discovery platform for viral infectious diseases, incorporating two key technologies: nucleoside analogs design technology and prodrug design technology. In particular, nucleoside analogs, through the function of polymerases, incorporate phosphorylated nucleosides into newly synthesized viral genomes, resulting in the termination of the viral DNA or RNA extension or induces lethal mutations, thereby exerting antiviral effects. However, the rational design of antiviral nucleoside analog presents significant challenges. We have synthesized numerous nucleoside analogs with diverse structures and conducted extensive antiviral activity studies targeting DNA and RNA viruses. Leveraging these studies, we have developed a nucleoside analogs design technology aimed at enhancing antiviral activity, minimizing toxicity, optimizing pharmacokinetic properties, and identifying scenarios where phosphorylation modifications are necessary.

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- ***Innovative drug discovery platform for neuropsychiatric disorders:*** With the aim to address challenges in developing effective therapies for neuropsychiatric disorders, we have independently developed a platform featuring core technologies including multi-target strategy-based drug discovery, diversified new drug *in vivo* evaluation system and enhanced compound BBB permeability. Specifically, the pathogenesis of neuropsychiatric disorders is complex, therefore, targeting a single pathway may not cure the diseases. Based on our insights of the pathogenesis of these diseases, we have identified appropriate target combinations and developed a multi-target strategy for innovative drug discovery. Using this technology, we have discovered VV119, a multi-target compound that target multiple pathways to exert a synergistic effect. In addition, developing animal models based on different causes and conducting comprehensive behavioral evaluations are key to improving the success rate of drug development in this area. We have successfully established a diversified *in vivo* evaluation system for new drugs targeting neuropsychiatric disorders, which enable us to systematically assess the efficacy of candidate compounds and comprehensively evaluate potential side effects during the preclinical stage. We have utilized our *in vivo* evaluation system as an integral part of our drug development process. For example, we have employed this system to evaluate the efficacy of LV232 and VV119.
- ***Innovative drug discovery platform for reproductive health diseases:*** Our drug discovery platform for reproductive health diseases features (i) pharmacokinetics-guided “structural fine-tuning” technology that aims to achieve an optimal balance of compound activity and pharmacokinetic properties and (ii) sexual dysfunction animal model construction technology with a variety of independently developed animal models to systematically evaluate the pharmacological efficacy of candidate compounds.
- ***“Control from root design” oriented green synthesis process R&D platform:*** Synthetic route design is the crucial element in the synthesis process of API. We have developed our “control from root design” oriented green synthesis process R&D platform, which primarily focuses on synthetic route design with a comprehensive consideration of regulatory requirements, chemical and process factors and environmental impact. By adopting our “control from root design” strategy, our synthesis processes and conditions reinforces our competitive edge within the industry and support green and sustainable development.

During the development of the synthetic process of the API for VV116, we developed a synthesis route, which reduced the production cycle by half, minimized the generation of nitrogen-containing pollutants, greatly lowered overall production costs compared to the initial synthesis route, and successfully achieved the one-time production of 500 kilograms of APIs in a single batch.

BUSINESS

Our proprietary technologies and pipeline assets are protected by a well-structured global patent portfolio across around 30 jurisdictions, which consisted of 39 registered patents and 35 patent applications in China, six registered patents and seven patent applications in the United States, 22 registered patents and 12 patent applications in Europe and Japan, three registered patents and nine patent applications in Uzbekistan and other “Belt and Road Initiative” countries, 11 registered patents and eight patent applications in other jurisdictions, and seven pending patent applications under PCT as of the Latest Practicable Date. In particular, we had 31 registered patents and 30 patent applications in connection with our Core Products.

We have a proven track record in successful clinical development and we are committed to bringing our drug candidates to the market in the most timely and cost-effective manner. Our clinical development team is highly experienced at formulating clinical development plans and determining optimal regulatory pathways. They design clinical development plans based on the mechanism of action and molecular characteristics of the drug candidate, the epidemiological features of the disease, as well as clinical treatment practices and medical needs. They are highly proficient in applying advanced MIDD to guide clinical design and decision-making. Also, our clinical development team possesses strong execution capabilities, ensuring that multi-center clinical trials are conducted in a scientifically rigorous, standardized and efficient manner. In addition, their rich experience in regulatory communication also plays a key role in advancing our clinical development plans towards successful commercialization. As a testament to our rationally designed clinical plans, for the clinical development of VV116 in RSV infection, we have adopted quantitative pharmacology modeling and simulation techniques and constructed PopPK and PBPK models to directly enter pediatric clinical trials. We believe this will substantially expedite the clinical advancement of VV116, accelerating the path toward its potential future launch.

GMP-standard commercial-scale in-house manufacturing capability, ensuring stable and cost-controllable supply

We have established an in-house manufacturing facility located in Lianyungang, Jiangsu Province, with an aggregate GFA of approximately 51,955 sq.m. This manufacturing facility has one workshop for small molecule drugs in oral solid dosage forms and one workshop for APIs. With an annual designed manufacturing capacity of 100 million capsules and 600 million tablets, our in-house manufacturing facility was designed and constructed in accordance with the GMP requirements and has been validated through the commercial-scale manufacturing of our approved drug. We have also implemented comprehensive quality control procedures and protocols to ensure the quality of products across the entire manufacturing lifecycle. Our manufacturing team is led by Dr. YANG Rulei, who has more than 10 years of industry experience at prominent pharmaceutical companies including Suzhou Kelun Pharmaceutical Research Co., Ltd. (蘇州科倫藥物研究有限公司), Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (正大天晴藥業集團股份有限公司) and Suzhou Suncadia Biopharmaceutical Co., Ltd. (蘇州盛迪亞生物醫藥有限公司) (a wholly-owned subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江蘇恒瑞醫藥股份有限公司)). As of September 30, 2024, we had 47 manufacturing, quality control and quality assurance personnel.

BUSINESS

We believe that our in-house GMP-standard manufacturing capability enhances the efficiency of our development and manufacturing processes, allowing us to achieve reliable quality and cost control and ensure stable and timely clinical and commercial drug supply to weather any supply chain disruptions. We pay close attention to the evolving standards and regulatory developments in the target markets and update our internal procedures accordingly, striving for the highest standards in patient safety and regulatory compliance. In addition, our in-house GMP-standard manufacturing capability will continue to serve as a bedrock for our capability to rapidly respond to evolving and unanticipated public health emergencies.

Strong commercial capabilities to facilitate effective market entry and penetration

We place great emphasis on business development and commercialization. Our business development and commercialization team is led by Dr. Zhang Zhenshan, an industry veteran with approximately 20 years of industry experience at reputable pharmaceutical companies such as Roche and Fosun Pharma. As of September 30, 2024, our business development and commercialization team consisted 14 employees with an average of more than 13 years of industry experience. Our commercialization efforts are built upon prominent academic influence and broad recognition by the medical community. Therefore, we engage in academic promotion to increase the market awareness of our drugs and drug candidates. We cooperate with leading Grade III hospitals in China to conduct clinical trials for our drug candidates, and we also work closely with renowned physicians in the industry to keep KOLs updated with the progress of our R&D. We believe that our in-house commercial capabilities will provide strong support for the upcoming commercialization of our drug candidates.

We foster an open and collaborative mindset and proactively pursue licensing and collaboration arrangements with leading industry players to maximize the clinical and commercial value of our assets. We entered into out-licensing agreements with Junshi Biosciences. See “— Collaboration Arrangement” for more details. We have also established strategic partnerships with leading academic and research institutions in China. We believe these strategic partnerships represent industry validation of our R&D capabilities and pipeline assets.

In response to the “Belt and Road Initiative” of the PRC government, we have developed a global commercialization strategy with our first successful attempt being the commercialization of VV116 and TPN171 in Uzbekistan. Leveraging our global patent portfolio, we believe that we are well positioned to continue to expand our footprint in overseas markets.

We believe that our strong commercial capabilities will not only facilitate effective market entry and penetration for our drugs in commercial or near-commercial stage, enhance our market awareness and reputation, but also allow us to continue to seek and capture value-accretive partnership opportunities, providing a solid foundation for our continued innovation and long-term growth.

BUSINESS

Visionary management team with rich industry experience and scientific expertise, backed by well-known investors

We are led by our visionary and seasoned founders and management team. Dr. Shen, one of our founders, is a renowned scientist in development of small molecule drugs with more than 30 years of industry experience. Dr. Shen is a researcher, group leader, and doctoral supervisor at the Shanghai Institute of Materia Medica, CAS. He has been selected as a “State Council Special Allowance Expert (國務院特殊津貼專家)” and been appointed as a honorary professor of Samarkand State University. He has received the “Excellent Supervisor Award of the CAS (中國科學院優秀導師).” In addition, Dr. Shen was awarded the “Most Beautiful Scientific and Technological Worker in Shanghai (上海市最美科技工作者)” by six governmental departments in Shanghai. As our founder, Dr. Shen contributed substantial resources and expertise during the initial stage of our operations and played a vital role in forming our business directions and strategies. We benefit from the high-level guidance and advice from Dr. Shen as our Controlling Shareholder.

Dr. Tian, our founder, chairman of the Board, executive Director, chief executive officer and general manager of our Company, has more than 20 years of industry experience. Dr. Tian has been appointed as an industrial professor by Suzhou University and was awarded as a “Key Industry Urgently-needed Talent (重點產業緊缺人才)” by government authorities. In addition, Dr. Tian led or participated in a number of national scientific research projects, such as Major Science and Technology Special Project for “Significant New Drugs Development” (“重大新藥創制”科技重大專項) and the National High-tech R&D Program (“863 Program”). Dr. Tian obtained his doctor’s degree in medicinal chemistry from Shanghai Institute of Materia Medica, CAS. Dr. Hu Tianwen, an executive Director and our deputy general manager mainly responsible for the management and R&D strategy of our Group, has more than 10 years of industry experience. As a prolific author, Dr. Hu has published more than 20 Science Citation Index (SCI) research papers. In addition, Dr. Hu has participated in a number of provincial science and technology projects as project leaders or core members. Dr. Hu obtained his doctor’ degree in organic chemistry from the Xinjiang Technical Institute of Physics and Chemistry Technology of the CAS. Dr. WANG Zhiqiang, our deputy general manager mainly responsible for the supervision and execution of clinical trials, has more than 20 years of industry experience. Dr. Wang has led the clinical development and regulatory submissions for more than 10 innovative drugs. Dr. Wang obtained his doctor’s degree in pharmacology from China Pharmaceutical University.

Our senior management team possesses an average of 17 years of industry-related or professional management experience. We believe that the experience and expertise of our management team will continue to drive our future growth.

Our Shareholders include a number of well-known investors who recognize our achievements and are confident in our growth potential. Together, our Shareholders provide us with professional insights and crucial connections to the biopharmaceutical industry in China and worldwide.

BUSINESS

OUR STRATEGIES

Rapidly advance the clinical development of our drug candidates

We plan to rapidly advance the clinical development of our drug candidates to achieve commercialization. We will also explore opportunities for indication expansion, aiming to maximize the therapeutic benefits of our pipeline assets for a broader patient population. In particular:

- **VV116.** We are currently conducting a Phase II/III clinical trial of VV116 in RSV-infected patients aged one to 24 months in China. We expect to complete the ongoing Phase II clinical stage of this trial in the second quarter of 2025 and initiate the Phase III clinical study in the third quarter of 2025. We expect to complete the registrational Phase III clinical study in the second half of 2026. We plan to expand the approved patient populations of VV116 for RSV infection after securing initial NDA approval.
- **LV232.** We plan to initiate the Phase II clinical trial of LV232 for the treatment of depressive disorder in China in the first quarter of 2025, with the trial expected to be completed in the second half of 2026. We expect to initiate a Phase III clinical trial of short-term usage of LV232 in China in the second half of 2026.
- **TPN171.** We filed an NDA for TPN171 for the treatment of ED in China in September 2023, and we anticipate to obtain NDA approval around mid-2025. We plan to develop a sublingual and buccal mucosal dosage form for TPN171. We also plan to initiate preclinical studies to explore indication expansion opportunities for TPN171.
- **VV261.** We are currently conducting a Phase I single dose-escalation study of VV261 in healthy subjects in China. Additionally, we plan to initiate a multiple dose-escalation study and a series of Phase I clinical trials to thoroughly evaluate the safety, tolerability, PK and food effects of VV261 in healthy subjects, as well as in elderly individuals, patients with mild to severe liver impairment, and patients with mild to severe renal impairment. The key clinical trials providing essential data for the initiation of a Phase II trial are anticipated to be completed in the first half of 2026. We intend to commence a Phase II clinical trial in the first half of 2027.

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- **TPN102.** We have completed a Phase I single dose-escalation study of TPN102 in healthy subjects in China. Moving forward, we plan to initiate a multiple dose-escalation study and a series of Phase I clinical trials to comprehensively evaluate the safety, tolerability, PK and food effects of TPN102 in healthy subjects, as well as in elderly individuals, patients with mild to severe liver impairment, and patients with mild to severe renal impairment. The key clinical trials providing essential data for the initiation of a Phase II trial are anticipated to be completed in the second half of 2026. We intend to commence a Phase II clinical trial in the first half of 2027.
- **VV119.** We are currently conducting Phase I single and multiple dose-escalation studies of VV119 in healthy subjects and adult patients with schizophrenia in China. Additionally, we plan to initiate a series of Phase I clinical trials to comprehensively evaluate the safety, tolerability, PK and food effects of VV119 in healthy subjects, as well as in elderly individuals, and patients with mild to severe liver impairment or mild to severe renal impairment. The key clinical trials providing critical data for the initiation of a Phase II trial are anticipated to be completed in the fourth quarter of 2025. We intend to commence a Phase II clinical trial in the first half of 2026.

In addition, we plan to continue to actively advance the development of our preclinical stage drug candidates towards IND submission.

Continue to enhance our R&D capabilities and further expand our pipeline

We believe continuous innovation is critical to our competitiveness and sustainable growth. Leveraging our proprietary technology platforms, we plan to actively invest in in-house discovery to seize market opportunities and to identify and develop innovative small molecule drugs targeting unmet clinical needs in our strategically focused therapeutic areas. We also intend to explore opportunities to develop RNAi therapies. We are in the process of establishing a new R&D center in Suzhou to further enhance our R&D capabilities.

We place a strong emphasis on talent recruitment and retention. We will continue to invest in attracting and retaining R&D professionals with complementary skillsets in key aspects of our drug development process. We will continue to provide our R&D team with systematic training and development programs to not only sharpen their technical skills but also help them stay abreast of industry developments.

In addition, we may continue to explore opportunities to engage in joint collaborations with leading universities and research institutions to develop new technologies or drug candidates.

BUSINESS

Further enhance our GMP-compliant manufacturing capability

We plan to continue to enhance our manufacturing capability through expanding our in-house capacity. Specifically, considering the favorable support from local government, we are in the process of establishing a new manufacturing facility in Qingdao in accordance with international GMP standards. With a GFA of approximately 11,272 sq.m., this new manufacturing facility is expected to intended to support our efforts in exploring formulation and indication expansion opportunities. With such manufacturing facility, we will be able to establish a dual north-south manufacturing network, further enhancing our manufacturing efficiency and improving the accessibility of our drugs. Meanwhile, we strive to continue to upgrade and improve our quality control practices to ensure patient safety and regulatory compliance.

Continue to strengthen our commercial capabilities and explore partnership opportunities to maximize the value of our pipeline assets

In anticipation of the expected approval timelines of our Core Products, we will implement a phased strategy to scale up our commercial capabilities to effectively meet significant post-launch market demand. We plan to progressively expand our business development and commercialization team and recruit additional sales and marketing personnel to provide dedicated coverage of medical institutions, retail pharmacies and other offline and online sales channels across China.

We will continue to refine our commercialization strategies and invest in marketing and promotion activities. For example, we plan to enhance our academic promotion efforts to deepen our market penetration and strengthen our relationships with leading physicians and hospitals. We may also seek partnerships with recognized players in the industry that will offer us access to their networks and resources.

We plan to continue to actively explore business collaboration opportunities and expand our global footprint. We will continue to pursue a flexible strategy to capture the commercial value in overseas markets, through forging synergistic license and collaboration opportunities worldwide. We will closely monitor and keep abreast of the evolving clinical demands and may also explore opportunities to in-license drug candidates that are complementary to our pipeline. In addition, we may selectively acquire or invest in innovative technologies to enhance our research and development capabilities. Furthermore, to support our global commercialization strategy, we will attract and retain managerial and technical talent with extensive international experience. As our business continues to grow, we remain committed to our mission of innovating for better health and quality of life for all patients in China and worldwide.

BUSINESS

OVERVIEW OF OUR PIPELINE

Our innovative products in commercialization stage include:

- **Viral Infection Sector:** VV116 is an innovative RdRp inhibitor approved for the treatment of COVID-19 in China and Uzbekistan under the trade names 民得維® and MINDVY®, respectively. The therapeutic efficacy of VV116 has garnered global attention, with 13 research papers published in prestigious journals such as The New England Journal of Medicine and The Lancet Infectious Diseases. To advance its global reach, we out-licensed the rights to research, develop, manufacture, and commercialize VV116 in specific countries and regions including China, to Junshi Biosciences. Additionally, we entered into a collaboration agreement with the Xinjiang Technical Institute of Physics and Chemistry, CAS, to co-develop VV116 in Uzbekistan; and
- **Reproductive Health Sector:** TPN171 is a potential best-in-class, highly selective, highly potent PDE5 inhibitor for the treatment of ED. Approved in Uzbekistan under the trade name ONVITA® in 2022, TPN171 boasts a novel chemical structure and offers multiple advantages, including high activity, high selectivity, good safety, significant efficacy, simple structure, and ease of synthesis. These attributes position it as a potential best-in-class PDE5 inhibitor.

Our innovative pipeline programs under development include:

- **Viral Infection Sector:** Beyond its application in COVID-19, we are advancing the clinical development of Core Product VV116 dry suspension for RSV treatment. Two Phase I clinical trials of VV116 dry suspension have been successfully completed in healthy adult subjects, and a Phase II/III clinical trial is currently underway in hospitalized infants and young children aged one to 24 months infected with RSV. Additionally, we are developing two pipeline product candidates: VV261 for the treatment of SFTSV infection, and VV207 for the treatment of adenovirus infection. Both candidates are nucleoside prodrugs. As of the Latest Practicable Date, VV261 was in Phase I clinical development, while VV207 was at the preclinical stage;
- **Neuropsychiatry Sector:** We are developing four innovative pipeline candidates for the treatment of neuropsychiatric disorders, including our Core Product LV232 as well as TPN102, VV119 and VV147. Our Core Product LV232 is a potential first-in-class dual-target 5-HTT/5-HT₃ receptor modulator for the treatment of depression. It has a unique mechanism of action to address a broader range of conditions with reduced adverse events, positioning it as a potential first-in-class treatment for depressive disorder and for improving emotional, anxiety, and pain-related comorbidities associated with depression. We have completed two Phase I trials of LV232 in healthy subjects and we plan to initiate the Phase II clinical trial of LV232 for the treatment of depressive disorder in China in the first quarter of 2025.

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TPN102 is a voltage-gated sodium and calcium channels inhibitor for the treatment of epilepsy. It exhibited improved therapeutic effect compared to first-line antiepileptic drugs according to our preclinical studies. VV119 is a multi-target compound for the treatment of schizophrenia by normalizing serotonergic and dopaminergic system dysfunction in the brain. According to our preclinical studies, VV119 exhibited robust efficacy in addressing the positive symptoms, negative symptoms, and cognitive dysfunction associated with schizophrenia, while also demonstrating a favorable safety profile. VV147 is developed for the treatment of depressive disorder. Preclinical data showed that VV147 exhibited significant antidepressant-like effects in multiple animal models, with potential for rapid onset of action. Additionally, it did not display addictive-like properties and had a favorable safety profile. As of the Latest Practicable Date, TPN102 and VV119 were in Phase I clinical trials, and VV147 was in preclinical stage; and

- **Reproductive Health Sector:** In addition to securing the marketing approval of TPN171 in Uzbekistan, we are actively advancing Core Product TPN171 for the treatment of ED in China. According to the completed clinical trials for ED, clinical indicators, including IIEF-EF, penile penetration success rate (SEP2), and erectile maintenance success rate (SEP3), were significantly improved in treatment groups with different doses of TPN171, compared to the placebo groups. As of the Latest Practicable Date, we have completed the registrational Phase III clinical trial of TPN171 for the treatment of ED in China, and expect to obtain the marketing approval from the NMPA around mid-2025. VV913 is developed for the treatment of premature ejaculation. Preclinical studies suggested that it achieved encouraging therapeutic effects with reduced side effects, enabling on-demand dosing to potentially improve patients’ quality of sex life. As of the Latest Practicable Date, VV913 was in the preclinical stage.

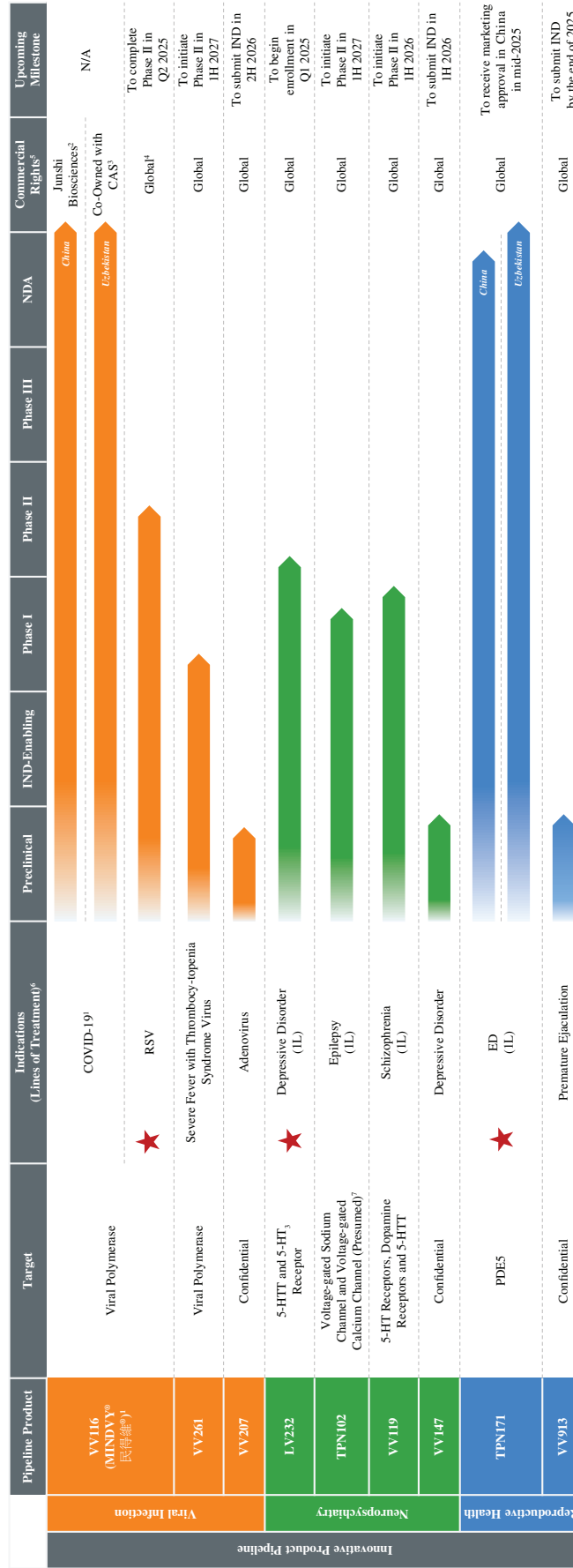
In addition to our innovative pipeline products, our product pipeline also includes four generic products. As of the Latest Practicable Date, we obtained marketing approvals for two generic drugs dapoxetine and rebamipide, and are developing two generic pipeline product candidates, i.e. breprazole and letermovir. As of the Latest Practicable Date, we had submitted ANDA for Breprazole and were advancing letermovir in the laboratorial development stage.

OUR INNOVATIVE PRODUCT PIPELINE

We have strategically selected and focused on three therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health. Antiviral drugs, which target widespread and potentially life-threatening diseases, constitute an important portion of the pharmaceutical industry in China. Neuropsychiatric drugs, driven by a large patient population and high treatment demand, ranked sixth in sales in the pharmaceutical industry by sales in 2023, according to CIC. While the market for reproductive health drugs is comparatively smaller, it holds significant growth potential fueled by increasing public health awareness and improving living standards.

BUSINESS

To address these clinical needs, as of the Latest Practicable Date, we have built an innovative product pipeline consisting of nine candidates, including our Core Products VV116, LV232 and TPN171, early clinical-stage candidates such as VV261, TPN102 and VV119, as well as preclinical-stage candidates VV207, VV147 and VV913. The following chart illustrates our innovative product pipeline and summarizes the status of our approved products, as well as clinical-stage and preclinical stage product candidates as of the Latest Practicable Date:



★ Core Products

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Abbreviations: 1L = first-line; N/A = not applicable; 5-HTT = serotonin transporter; 5-HT₃ = 5-hydroxytryptamine 3; PDE = phosphodiesterase; CDE = Centre for Drug Evaluation; IND = investigational new drug application; RSV = respiratory syncytial virus; ED = erectile dysfunction; Q2 = second quarter; 1H = first half; 2H = second half; mid-2025 = second to third quarter of 2025.

Notes:

1. VV116 received conditional marketing approval in China for the treatment of COVID-19 under the trade name 民得維® in January 2023, and received full approval in January 2025, and secured marketing approval in Uzbekistan for the treatment of moderate and severe COVID-19 under the trade name MINDVY® in December 2021.
2. We co-discovered VV116 in collaboration with Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS. We acquired exclusive global intellectual property rights related to VV116 from Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS. For details, see “— Collaboration Arrangement — VV116 Agreements.” Starting in September 2021, we entered into a series of agreements with Junshi Biosciences, granting exclusive global rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19, with the exception of five countries in Central Asia (Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan), and Russia. For details, see “— Collaboration Arrangement — VV116 Agreements.”
3. Under a co-development agreement, we jointly own the rights to research, develop, manufacture, and commercialize VV116 for COVID-19 treatment with the Xinjiang Technical Institute of Physics and Chemistry, CAS in five Central Asian countries (Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan). For details, see “— Collaboration Arrangement — VV116 Agreements.”
4. We were heavily involved in the development of VV116 for the treatment of COVID-19 and are currently conducting clinical development for the treatment of RSV infection in China.
5. We hold exclusive global rights to research, develop, manufacture, and commercialize TPN171, LV232, VV261, TPN102, VV119, and VV913. We discovered and are internally developing VV119. For TPN171 and LV232, our founder Dr. Tian has made significant contributions to their discovery while he was working at Topharman Shanghai. We acquired exclusive global intellectual property rights related to TPN171 from Shanghai Institute of Materia Medica, CAS, Topharman Shanghai, and Shandong Topharman and acquired exclusive global intellectual property rights related to LV232 from Shanghai Institute of Materia Medica, CAS, and Topharman Shanghai. For details, see “— Collaboration Arrangement.” For VV261, TPN102, and VV913, we co-discovered these products with Topharman Shanghai and/or Independent Third Party partners, and subsequently acquired exclusive global rights. Regarding VV207 and VV147, we co-discovered these candidates with Independent Third Party partners and jointly own the global rights to research, develop, manufacture, and commercialize them.
6. Except for depressive disorder, epilepsy, schizophrenia and ED, currently there are no guidelines with respect to the treatment lines of the other indications targeted by our pipeline products, according to CIC.
7. According to preclinical studies, TPN102 demonstrated inhibitory activity on two ion channel receptors — sodium and calcium channels — at micromolar levels *in vivo*. Furthermore, TPN102 exhibited significant antiepileptic effects in various animal models of epilepsy, suggesting that both sodium and calcium channels may be the potential targets for TPN102. Based on data observed in these preclinical studies, as of the Latest Practicable Date, we believed that TPN102 targeted sodium and calcium channels.

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INNOVATIVE DRUG CANDIDATES

Core Product — VV116 — RNA-Dependent RNA Polymerase Inhibitor

Our Core Product VV116 is a RdRp inhibitor, which has been approved for the treatment of COVID-19 in China and Uzbekistan under the trade names 民得維[®] and MINDVY[®], respectively, and is under Phase II/III clinical development for the treatment of RSV in China. RdRp is an enzyme that catalyzes the replication of RNA from an RNA template and is highly conserved in viruses. By inhibiting RdRp function, new RNAs cannot be replicated from an RNA template strand, thereby disrupting the replication of RNA viruses. The therapeutic efficacy of VV116 for the treatment of COVID-19 was well evidenced by its Phase III clinical results. In particular, data showed that among adults with mild-to-moderate COVID-19 who were at risk for progression, VV116 was noninferior to Paxlovid with respect to the time to sustained clinical recovery, with fewer safety concerns. These findings were published in influential journals, including The New England Journal of Medicine and The Lancet Infectious Diseases.

As an RdRp inhibitor, VV116 holds significant potential for the treatment of infectious diseases caused by various known RNA viruses, including RSV, Zika virus, Ebola virus, as well as other types of corona viruses such as OC43 and 229E. Its potential has been preliminarily proved through *in vitro* studies. In addition, VV116 also demonstrated synergistic effects with other antiviral drugs, such as nirmatrelvir, a 3C-like protease inhibitor, indicating its potential to serve as a backbone drug in the antiviral field.

VV116 received conditional marketing approval as a Class I innovative drug for the treatment of mild to moderate COVID-19 in China in January 2023, and received full approval in January 2025. Additionally, VV116 secured marketing approval for the treatment of moderate or severe COVID-19 in Uzbekistan in December 2021.

To address the significant clinical need for effective antiviral treatments for RSV infections, we are investigating VV116 for this indication. Considering a significant portion of vulnerable patient populations, particularly infants and young children, may experience swallowing difficulties, we have developed VV116 as an oral dry suspension. This formulation is designed to offer improved medication compliance compared to tablets and capsules. In May 2023, we received IND approval from the NMPA to conduct Phase I clinical trials of VV116 dry suspension. Based on the clinical data collected from Phase I trials of VV116 dry suspension, as well as from previous clinical trials of VV116 for COVID-19, we obtained regulatory clearance from the NMPA, and initiated a Phase II/III clinical trial for the treatment of hospitalized infants and young children aged one to 24 months infected with RSV in China. As of the Latest Practicable Date, the Phase II/III clinical trial was ongoing in China.

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Packaging of 民得維®



Packaging of MINDVY®

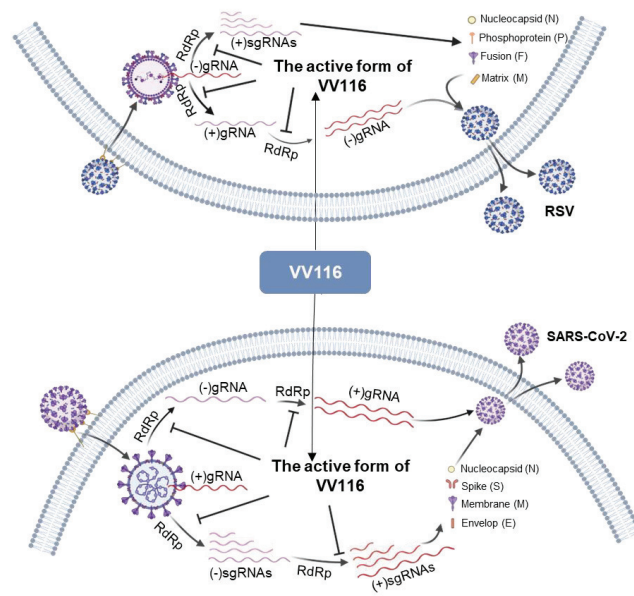


Source: Company data

Mechanism of Action

RdRp is an enzyme that catalyzes the replication of RNA from an RNA template. Different from DNA-dependent RNA polymerase that catalyzes the transcription of RNA from a DNA template, it catalyzes synthesis of the RNA strand complementary to a given RNA template. RdRps are highly conserved in viruses. Halting the extension of viral RNA or inducing lethal mutations can effectively disrupt the replication of RNA viruses, thereby producing a strong antiviral effect.

VV116 is a Class I innovative drug that targets RdRp. The active triphosphate form of VV116 can be incorporated into nascent RNA chains by the RdRp, which results in RNA elongation stalling.



Source: China Insights Consultancy

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Market Opportunities and Competition

VV116 has the potential to be a broad-spectrum antiviral drug to protect human from being infected by various known RNA viruses, including RSV, COVID-19, Zika virus, Ebola virus, as well as other types of coronaviruses, such as OC43 and 229E. Currently, VV116 received marketing approvals, for the treatment of COVID-19 in China and Uzbekistan, and is under clinical development for the treatment of RSV in China.

RSV

RSV is a non-segmented, negative-sense, single-stranded RNA virus that primarily spreads through hands, fomites, and aerosols. The global prevalence of RSV is expected to increase from 136.2 million in 2023 to an estimated 157.0 million in 2035, with a CAGR of 1.2%. In China, the prevalence rose from 25.5 million in 2023 to 26.2 million in 2035, with a CAGR of 0.2%. In China, infants and young children aged one to 24 months account for approximately 30.6% of the RSV patient population.

Currently, the standard treatment for RSV is primarily supportive care, including oxygen supplementation, nasal decongestants, hydration and nutrition, along with the use of bronchodilators, epinephrine and steroids. For pediatric RSV infections, clinical treatment options include interferon, ribavirin and bronchodilators, though routine use of ribavirin is not recommended due to significant side effects and insufficient evidence supporting its efficacy in treating RSV. In adults, treatment for RSV infection is largely confined to supportive care, such as bronchodilators, supplemental oxygen, intravenous infusions and antipyretics.

According to the latest Guidelines for the Treatment and Prevention of Lower Respiratory Tract Infections Caused by Human Respiratory Syncytial Virus (2024 Edition), the efficacy of antiviral drugs such as ribavirin remains unclear, and their potential side effects make them unsuitable for routine use. Additionally, medications like corticosteroids and bronchodilators have limited effectiveness in treatment and should be used with caution. Therefore, there is an urgent need for innovative therapeutic options to treat RSV infections.

The development of therapeutic products for RSV treatment represents a significant unmet medical need on a global scale. However, as of the Latest Practicable Date, no effective small molecule antiviral therapeutic products for RSV treatment were available worldwide. With the approval of the first innovative small molecule antiviral therapy anticipated in 2026, the global market is expected to reach US\$6.7 million in 2026 and grow substantially to US\$879.7 million by 2035. Similarly, the market size in China is expected to reach RMB46.7 million in 2026 and increase to RMB1,067.0 million in 2035.

Worldwide, six small molecule antiviral drug candidates were under development for RSV treatment. In China, two small molecule antiviral drug candidates were in development for RSV treatment. Among these candidates, VV116, was the only candidate targeting RdRp in China. VV116 dry suspension also stood out as the only dry suspension formulation designed for convenient administration to infants and young children, which was in a Phase II/III clinical trial as of the Latest Practicable Date. For the detailed information regarding the competitive landscape of RSV treatment, see “Industry Overview — Innovative Small Molecule Drug Industry — Antiviral Drugs — RSV Drugs.”

BUSINESS

COVID-19

SARS-CoV-2, which caused the COVID-19 pandemic, is a positive-sense, single-stranded RNA virus that primarily affects the respiratory system, causing flu-like symptoms such as cough, fever, muscle pain, and difficult breathing. According to the WHO, there were more than 700 million cases of COVID-19 worldwide from its outbreak until 2024.

Currently, the recommended antiviral treatment of COVID-19 is still small molecule drugs. Antiviral medications are administered to inhibit viral replication and reduce viral load. In severe and critical cases, corticosteroids, IL-6 inhibitors, and baricitinib can be recommended in combination with antiviral medications. However, current COVID-19 treatments face limitations in efficacy, side effect risks, drug resistance, unequal access, and high costs. Additionally, viral mutations, a lack of long-term data, individual variability, and complex immune responses further complicate effective treatment.

As of the Latest Practicable Date, 10 small molecule antiviral drugs were fully approved or conditionally approved globally for the treatment of COVID-19, with two of them having received full marketing approval in China. 民得維®/MINDVY® was the only product that has gained full approval both in China and internationally.

Globally, Veklury (remdesivir) accounted for nearly half of the small molecule COVID-19 drug market in 2023, followed by Lagevrio, Paxlovid, Xocova, and Xiannuoxin. In China, Paxlovid led the market with a 58% share in 2023, while 民得維® ranked in the top five in terms of sales. Globally and in China, the top five players together account for nearly 100% of the market share in terms of sales in 2023. For the detailed information regarding the competitive landscape of COVID-19 treatment, see “Industry Overview — Innovative Small Molecule Drug Industry — Antiviral Drugs — COVID-19 Drugs.”

Competitive Advantages

VV116 is a broad-spectrum antiviral nucleoside drug that inhibits the RdRp of viruses to exert its antiviral effects. Its safety has been rigorously evaluated in at least 12 clinical trials conducted in China and in real world patients, involving a total of at least 9,000 healthy individuals and patients, with results confirming a favorable safety profile. Based on data collected from previous clinical trials and real-world patients as of the Latest Practicable Date, VV116 carries no risk of mutagenicity and poses no risk of severe adverse reactions caused by interactions with other drugs. It can be rapidly absorbed when taken orally, demonstrates high bioavailability, and can be administered under fasting or regular dietary conditions. As a drug approved for marketing in both China and Uzbekistan, VV116 has demonstrated robust efficacy in the treatment of COVID-19. The Phase III clinical trial results were published in influential journals, including The New England Journal of Medicine and The Lancet Infectious Diseases.

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Additionally, its potential to treat RNA viruses, such as RSV, along with its synergistic antiviral effects when combined with other antiviral agents, has been preliminarily validated in preclinical studies. These findings underscore its significant market potential to address extensive clinical needs.

VV116 Showed Favorable Safety and Efficacy Profile for COVID-19 Treatment

VV116 is a prodrug of deuterated nucleoside with improved oral bioavailability and potent anti-SARS-CoV-2 activity. Preclinical and clinical studies have shown that VV116 has substantial antiviral effects against the original and mutant strains of COVID-19, including Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), and Omicron (Omicron BA.2, BA.2.12.1, BA.4, and BA.5), without causing genotoxicity. Moreover, three Phase I studies among healthy individuals revealed satisfactory safety and pharmacokinetic profiles for VV116.

Based on a double-blind, placebo-controlled, randomized, Phase III study of VV116 for the treatment of COVID-19 in approximately 1,369 patients, a 5-day treatment with VV116 significantly shortened the time to sustained clinical symptom resolution and clinical symptom alleviation in patients with mild-to-moderate COVID-19 compared to placebo group. At the start of the trial, although three antiviral drugs were already conditionally approved for marketing in China for treating COVID-19 in adults, they had not been evaluated in patients infected with the Omicron variant. In this Phase III study, a total of 150 patients were tested positive for SARS-CoV-2 genetic variation at enrolment and all were found to be infected with the SARS-CoV-2 Omicron variants, with BA.5.2.48 (n=88, 58.7%) and BF.7.14 (n=46, 30.7%) as the leading subvariants.

The final analysis showed that VV116 is effective for the treatment of COVID-19, including Omicron variants. The time to sustained clinical symptom resolution for two consecutive days was substantially reduced in the treatment group compared with the placebo group (median time 10.9 days vs 12.9 days). Among patients aged 60 years and older, the median time to sustained clinical symptom resolution and sustained clinical symptom alleviation was shorter in the treatment group compared with the placebo group, which is consistent with the overall population. Meanwhile, the subgroup analysis in male and female patients showed similar treatment efficacy.

Overall, VV116 was well tolerated in patients with mild-to-moderate COVID-19. The incidence of treatment-emergent adverse events was 35.9% in the treatment group and 42.1% in the placebo group and the incidence of treatment-related adverse events was 17.4% in the treatment group and 23.2% in the placebo group, which could be attributed to VV116's ability to inhibit viral replication, potentially reducing illness or symptoms caused by the SARS-CoV-2 infection. Most of the treatment-emergent adverse events in this study were laboratory abnormalities and ranged between Grades 1 and 2. In this study, only one patient from the placebo group progressed to severe COVID-19. Among patients aged 60 years and older, the incidence of treatment-emergent adverse events was similar to that in the overall population. Increased blood pressure was the most frequently reported treatment-emergent adverse event in both the overall population and patients aged 60 years and older. No new safety signals were found in patients aged 60 years and older.

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In summary, VV116 produced a significant reduction in the time to sustained clinical symptom resolution compared with placebo in patients with mild-to-moderate COVID-19, with a low incidence of adverse events and a favorable safety profile. In January 2025, the NMPA fully approved VV116 for the treatment of patients with mild-to-moderate COVID-19 based on multiple clinical and non-clinical studies, including the a Phase III clinical trial and a real-world study involving approximately 8,000 patients.

Improved Properties than Other Approved COVID-19 Treatment Drugs

VV116 is featured by improved properties compared to Paxlovid and other COVID-19 treatment drugs. Paxlovid is an antiviral drug approved by the FDA for the treatment of COVID-19. The FDA also issued Emergency Use Authorizations to other drugs for COVID-19 treatment, including remdesivir, neutralizing monoclonal antibodies targeting the SARS-CoV-2 spike protein, as well as molnupiravir, which inducing lethal mutations in the SARS-CoV-2 viral genome and, eventually, full approval of the small molecule antiviral combination drug nirmatrelvir-ritonavir (i.e. the active pharmaceutical ingredients of Paxlovid), for patients who are at high risk for progression to severe COVID-19, including hospitalization or death.

Remdesivir requires intravenous administration and a Phase III study (i.e. PINETREE) excluded patients who had been vaccinated, with the study conducted before widespread infection by Omicron variants. Airmatrelvir-ritonavir contains ritonavir, a protease inhibitor that potentiates multiple known drug-drug interactions. Approximately 15% of patients with severe COVID-19 have medical contraindications for nirmatrelvir-ritonavir, with numbers reaching 26.9% in patients older than 65 years. These limitations reduce the number of COVID-19 patients eligible for Paxlovid treatment. Neutralizing antibodies are limited by their high treatment costs, strict transport and storage conditions, relative inconvenient intravenous administration method, and susception to viral escape mutations. As a result, neutralizing antibodies that were no longer effective against Omicron variants lost their US Emergency Use Authorizations. Phase II and Phase III studies have demonstrated that molnupiravir, an oral small molecule drug, effectively accelerated SARS-CoV-2 RNA clearance in patients with mild-to-moderate COVID-19. However, concerns persist regarding the safety of molnupiravir, a tautomerizing β -D-N4-hydroxycytidine-5'-isopropyl ester, particularly in relation to its potential genotoxicity and viral mutagenicity. There is a growing demand for a safer and more effective oral agent with broad-spectrum antiviral activity for the treatment of COVID-19.

According to an observer-blinded, Paxlovid-controlled, randomized, Phase III study of VV116 in patients with mild-to-moderate COVID-19 conducted by us, VV116 was noninferior to Paxlovid in reducing the time to sustained clinical symptom resolution among patients with mild-to-moderate COVID-19 at risk for progression with improved safety profile. In this study, we enrolled 771 patients, who received either VV116 (384 patients) or Paxlovid (387 patients). Among these patients, VV116 was observed to be noninferior to Paxlovid in reducing the time to sustained clinical symptom resolution among patients with mild-to-moderate COVID-19 at risk for progression (median time 7 days vs 7 days). No patients in either group had died or had had progression to severe COVID-19 by day 28. The incidence of adverse events was lower in the VV116 treatment group than in the Paxlovid treatment group (67.4% vs. 77.3%), as well as fewer Grade 3 or 4 adverse events (2.6% vs. 5.7%). The most frequently reported adverse

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events (occurring in $\geq 5\%$ of the patients in either group) were dysgeusia (3.6% with VV116 and 25.8% with Paxlovid), hypertriglyceridemia (10.7% and 20.9%, respectively), and hyperlipidemia (3.1% and 9.6%); all these frequent adverse events were nonserious.

Promising Therapeutic Effect For the Treatment of RSV

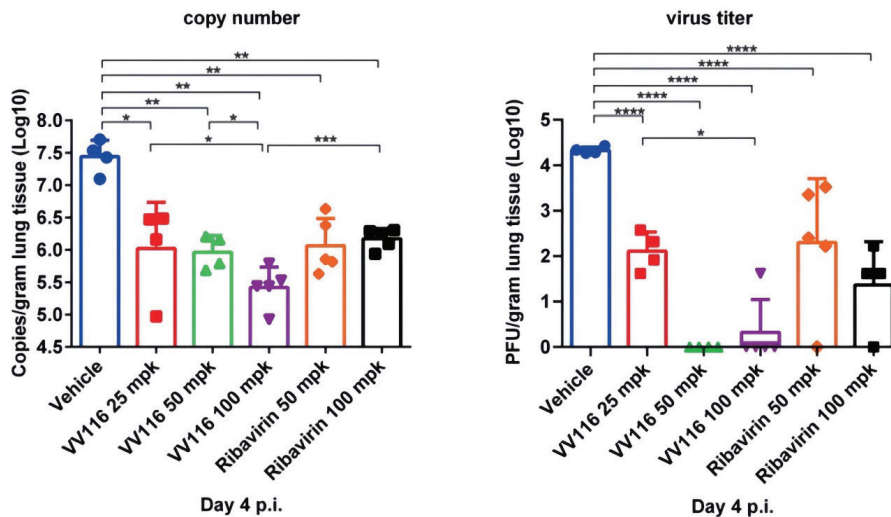
Currently, no effective antiviral treatments for RSV have been approved for marketing in China. Also, the latest Expert Consensus on the Diagnosis, Treatment, and Prevention of RSV Infections in Children does not recommend the routine use of ribavirin. As a result, there is an urgent clinical need for safe and effective antiviral drugs for RSV treatment.

VV116 exhibits strong *in vitro* inhibitory activity against RSV and demonstrates significant efficacy in animal models of RSV infection. Preclinical studies have shown that VV116 not only exhibited significant anti-RSV efficacy but also offered advantages such as favorable pharmacokinetic properties and high safety. In the human bronchial epithelial cells, the EC_{50} of VV116 against RSV can reach approximately 90 nM.

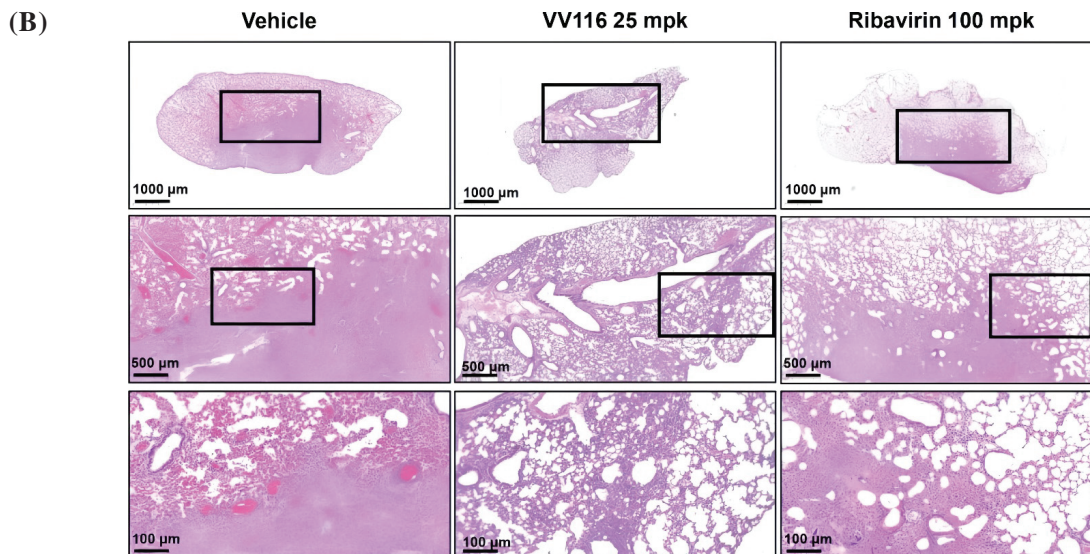
In the Balb/c mouse model, VV116 at doses of 25, 50, and 100 mg/kg significantly reduced the viral RNA copy numbers and viral titers in the lungs of mice. At a dose of 50 mg/kg, VV116 was able to reduce the viral titer to below the detection limit and showed significant improvement in the pathological changes of the lungs.

Efficacy of VV116 Against RSV Infection in Balb/c Mice

(A)



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Abbreviation: mpk = mg/kg.

Notes:

- (A) Viral RNA and infectious titer levels in lung tissues of vehicle-controlled, VV116- and Ribavirin- treated mice on day 4 post infection (p.i.). The significance of the difference between mean values was determined by Student's t test. * $p < 0.05$, ** $p < 0.005$, *** $p < 0.0005$, **** $p < 0.0001$.
- (B) Histopathology of the lungs of the vehicle-controlled, VV116- and ribavirin-treated mice for 4 days.

Source: Literature review

Preclinical studies showed that VV116 had no inhibitory effects on major drug-metabolizing enzymes or transporters and exhibited no genotoxicity. Results from a long-term (6-week) toxicity study in juvenile rats indicated that VV116 did not affect growth or development, with no unexpected toxicities observed.

In a completed Phase I clinical study conducted in healthy adult individuals in China, data demonstrated that co-administration of VV116 dry suspension with infant formula did not significantly affect the bioavailability of 116-N1. The trial also confirmed VV116's favorable safety profile, with all adverse drug reactions being Grade ≤ 2 in severity and no serious adverse events or Grade ≥ 3 adverse events reported. Furthermore, the incidence of adverse drug reactions showed no clear dose-dependent trend, underscoring its overall safety. These encouraging data warranted further clinical investigation of VV116 dry suspension in RSV-infected infants and young children.

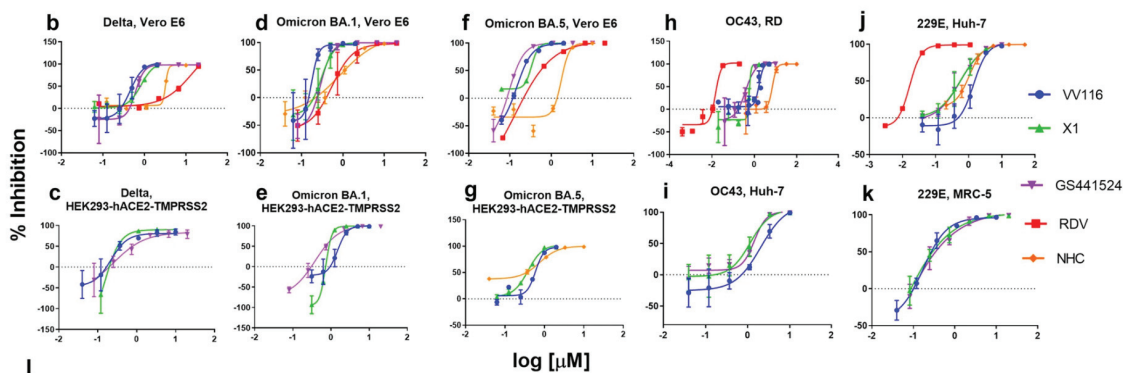
Potential as a Broad-Spectrum Antiviral Drug

Given that VV116 targets the highly conserved active site of RdRp, it is expected to exhibit the same level of inhibitory activity against future SARS-CoV-2 variants. Preclinical *in vitro* studies have demonstrated that VV116 possessed significant inhibitory activity against the original SARS-CoV-2 strain, various known variants, including Alpha, Delta, and Omicron, as well as other coronaviruses, such as OC43 and 229E.

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To evaluate VV116’s potential in inhibiting RNA viruses, preclinical studies were conducted using various cells lines. Cells were pre-seeded overnight, then the culture medium was removed and replaced with a medium containing VV116 for 1 hour incubation. Thereafter, cells were then inoculated with various coronaviruses. At 24 hours or 48 hours after infection, the supernatant was collected for viral RNA copy number determination using real-time fluorescence quantitative PCR. The inhibition rate of compounds was calculated based on the viral copy number, and the 50% effective concentration (EC_{50}) was calculated. These experiments were independently performed three to six times. Results of this study demonstrated that VV116 was a promising oral drug that can broadly suppress human coronaviruses including SARS-CoV-2 and its variants.

The activity of VV116 in Inhibiting SARS-CoV-2 Variants, HCoV-OC43, and HCoV-229E



Notes:

- X1 refers to VV116’s parent nucleoside
- GS441524 refers to main plasma metabolite of the antiviral prodrug remdesivir
- RDV refers to remdesivir
- NHC refers to β -d-N4-hydroxycytidine

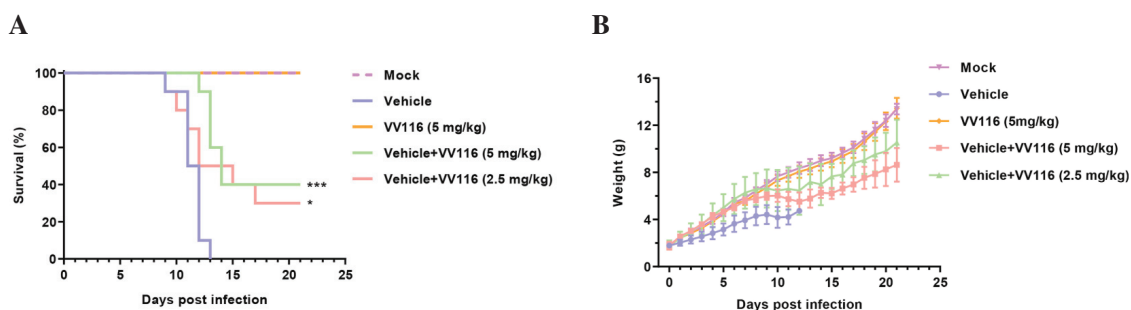
Source: Literature review

Furthermore, in addition to its activity against coronaviruses, *in vitro* studies have shown that VV116 also inhibited other RNA viruses, including Zika virus and Ebola virus. These findings suggest that the clinical application of VV116 could be significantly expanded to address challenging and high-risk viral infection, potentially including the treatment of co-infections involving multiple RNA viruses.

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The *in vivo* antiviral efficacy of VV116 against Zika infection was evaluated by analyzing the survival curve and body weight changes in 1-day-old ICR suckling mice. Intraperitoneal injections of varying concentrations of VV116 were administered, while the control group received a solvent. The mice were continuously treated for nine days, and their morbidity and weight changes were recorded daily until 21 days post-challenge. The results suggested that the treatment group receiving a dose of 5 mg/kg VV116 exhibited a 40% survival rate after the challenge, along with significant weight improvement.

Survival and Body Weight Curves of ZIKV-infected Mice



Notes: Changes in survival (A) and body weight (B) were recorded daily throughout the experimental period.

* $P < 0.05$ and *** $P < 0.001$.

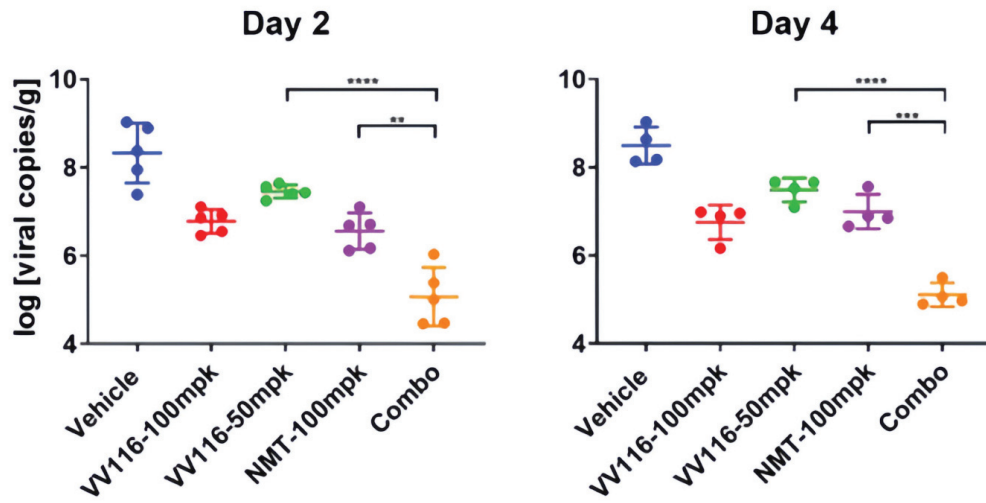
Source: Literature review

Potential as a Backbone Drug Combined with Anti-RNA Virus Therapies

VV116 was further evaluated in combination with nirmatrelvir against the SARS-CoV-2 Delta variant in a K18-hACE2 mouse model. Mice were intranasally infected with the SARS-CoV-2 Delta variant and, 2 hours post-infection, were orally administered vehicle, VV116, nirmatrelvir, or a combination of VV116 and nirmatrelvir. The results demonstrated that lung viral loads in the VV116 (50 mg/kg and 100 mg/kg) groups and the nirmatrelvir (100 mg/kg) group were reduced by 1–2 log-fold compared to the vehicle group at both 2 days post-infection (“dpi”) and 4 dpi. The co-administration of VV116 (50 mg/kg) and nirmatrelvir (100 mg/kg, along with 50 mg/kg ritonavir) significantly reduced lung viral loads more effectively than either VV116 or nirmatrelvir alone, achieving a 3 to 4 log-fold reduction in viral loads compared to the vehicle group at both time points.

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In Vitro Study of VV116 in Combination with Nirmatrelvir



Note: ** $P < 0.01$, *** $P < 0.001$, and **** $p < 0.0001$.

Source: Literature review

Improved Formulation

In order to better serve clinical needs of various patient populations of VV116, especially those who have swallowing difficulties, we have developed VV116 as an oral dry suspension, offering improved medication compliance compared to tablets and being particularly suitable for RSV-susceptible populations, such as infants, young children, and the elderly.

The results of a Phase I clinical trial in healthy adult subjects demonstrated that a single oral dose of VV116 dry suspension at 25, 100, and 300 mg resulted in a dose-proportional increase in C_{max} and AUC, consistent with linear PK. Additionally, infant formula did not impact the bioavailability of VV116. These promising findings, together with quantitative pharmacology modeling and simulation that extrapolate the first dose for RSV-infected children from adult doses, supported further clinical investigation in infants and young children with RSV infections. As of the Latest Practicable Date, a Phase II/III clinical trial of VV116 dry suspension was underway in hospitalized infants and young children aged one to 24 months infected with RSV in China.

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Summary of Selected Clinical Trial Results

Below is a summary of selected Phase I, Phase II and Phase III clinical trials of VV116. In particular, we have sponsored and conducted three Phase I clinical trials of VV116 tablets in healthy subjects and one Phase III clinical trial for the treatment of COVID-19 in China. Additionally, we have sponsored and conducted two Phase I clinical trials of VV116 dry suspension in healthy subjects and are currently conducting a Phase II/III clinical trial of VV116 dry suspension in RSV patients aged one to 24 months in China.

VV116 for COVID-19 treatment

Phase III Clinical Trial of VV116 in Patients with Mild-to-Moderate COVID 19

Trial design. This is a multi-center, observer-blinded, randomized, Paxlovid-controlled, Phase III clinical trial of VV116 during the outbreak caused by the B.1.1.529 (Omicron) variant of SARS-CoV-2 in patients with mild-to-moderate disease but at high risk for progression to severe Covid-19. The study was sponsored by us and conducted in China. 771 patients received treatment in this study. 384 of them were enrolled in the VV116 treatment group and 387 were enrolled in the Paxlovid treatment group. Patients received either oral VV116 (600 mg every 12 hours on day 1 and 300 mg every 12 hours on days 2 through 5) or oral Paxlovid (300 mg of nirmatrelvir plus 100 mg of ritonavir every 12 hours for 5 days).

Seven patients in the VV116 group were taking concomitant medications that have potential drug interactions with ritonavir (three were taking estazolam, one diazepam, and three nifedipine), and four of them (one taking estazolam and three nifedipine) had concomitant medications withheld during the active treatment phase. Seven patients in the nirmatrelvir-ritonavir group were taking concomitant medications that have potential drug interactions with ritonavir (three were taking estazolam and four nifedipine), and three of them (one taking estazolam and two nifedipine) had concomitant medications withheld during the active treatment phase.

The primary efficacy endpoint was the time from randomization to sustained clinical recovery through day 28. Sustained clinical recovery was defined as the alleviation of all COVID-19-related target symptoms to a total symptom score of 0 or 1 (range, 0 to 33, with higher scores indicating greater severity) for two consecutive days. Secondary efficacy endpoints included progression to severe or critical COVID-19 or death from any cause; the change in COVID-19-related symptom score and the score on the WHO Clinical Progression Scale through day 28, the time to sustained resolution of all target symptoms and to a first negative SARS-CoV-2 test, and clinical recovery, symptom resolution, and a negative SARS-CoV-2 test by prespecified days. Safety endpoints included adverse events and serious adverse events.

Trial Status. The study was initiated in April 2022, and completed in May 2022.

Safety Profile. Through 28 days of follow-up, patients who received VV116 reported fewer adverse events than those who received nirmatrelvir-ritonavir (67.4% vs. 77.3%), as well as fewer Grade 3 or 4 adverse events (2.6% vs. 5.7%). Two serious adverse events (acute

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cerebral infarction and a deterioration of the preexisting interstitial lung disease) were reported in two patients in the nirmatrelvir-ritonavir treatment group. One serious adverse event was reported in a patient in the VV116 treatment group who was readmitted for repeat positivity for SARS-CoV-2 on RT-PCR assay. None of the three serious adverse events were considered by the investigators to be related to the assigned drugs. The most frequently reported adverse events (occurring in $\geq 5\%$ of the patients in either group) were dysgeusia (3.6% with VV116 and 25.8% with nirmatrelvir-ritonavir), hypertriglyceridemia (10.7% and 20.9%, respectively), and hyperlipidemia (3.1% and 9.6%); all these frequent adverse events were nonserious. By the time of the final analysis, no patients in this trial had died or had had progression to severe COVID-19.

Summary of Safety Data

Adverse Events	VV116 (N=384)	Nirmatrelvir- Ritonavir (N=387)
	<i>no. of patients (%)</i>	
Adverse events overall		
Any adverse event	259 (67.4)	299 (77.3)
Adverse event with maximum Grade of ≥ 3 ¹	10 (2.6)	22 (5.7)
Serious adverse event ²	1 (0.3)	2 (0.5)
Adverse event leading to discontinuation of trial regimen	6 (1.6)	9 (2.3)
Adverse event leading to dose reduction or temporary discontinuation of trial regimen	5 (1.3)	4 (1.0)
Adverse events considered by the investigator to be related to the assigned regimen		
Any adverse event	199 (51.8)	260 (67.2)
Adverse event with maximum Grade of ≥ 3 ¹	7 (1.8)	20 (5.2)
Serious adverse event	0	0
Adverse event leading to discontinuation of trial regimen	6 (1.6)	9 (2.3)
Adverse event leading to dose reduction or temporary discontinuation of trial regimen	4 (1.0)	4 (1.0)

Notes:

- Severity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0. For events not listed in the NCI CTCAE, version 5.0, severity was determined according to prespecified criteria listed in the protocol.
- Serious adverse events included readmission for a newly positive RT-PCR result for SARS-CoV-2 (one participant in the VV116 group), acute cerebral infarction (one participant in the nirmatrelvir-ritonavir group), and deterioration of preexisting interstitial lung disease (one participant in the nirmatrelvir-ritonavir group). None of the events were considered by the investigator to be related to the assigned regimen.

Source: Literature review

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Efficacy Profile. The efficacy analysis demonstrated that the therapeutic effect of VV116 was equivalent to that of nirmatrelvir-ritonavir, satisfying the criteria for noninferiority. In the final analysis, the estimated median time to sustained clinical recovery was 4 days in VV116 treatment group and 5 days in the nirmatrelvir-ritonavir-treatment group, and the 25th percentile of the time to sustained clinical recovery was 4 days in both groups. Noninferiority of VV116 to nirmatrelvir-ritonavir was also observed in the per-protocol population among patients who started treatment within 5 days after symptom onset, and in the intention-to-treat population.

The estimated median time from randomization to sustained resolution of COVID-19-related target symptoms was 7 days in both groups. The percentage of patients with sustained clinical recovery was higher in the VV116 treatment group than in the nirmatrelvir-ritonavir treatment group by each prespecified time point. The median time from randomization to a first negative SARS-CoV-2 test was 7 days in both groups. The percentages of patients with negative SARS-CoV-2 tests by prespecified time points and the changes in viral cycle-threshold values and target symptom scores from baseline were similar in the two groups.

Summary of Primary and Secondary Efficacy Endpoints

Endpoints	VV116 (N=384)	Nirmatrelvir- Ritonavir (N=387)
Primary endpoint¹		
25th percentile of time to sustained clinical recovery (95% CI) — days	4.0 (3.0–4.0)	4.0 (3.0–4.0)
Median time to sustained clinical recovery — days	4.0	5.0
Hazard ratio vs. nirmatrelvir–ritonavir (95% CI) ²	1.17 (1.02–1.36)	–
Secondary endpoints		
Progression to severe Covid-19 or death by day 28 — no. (%)	0	0
Median time to sustained symptom resolution (95% CI) — days ³	7.0 (7.0–8.0)	7.0 (7.0–8.0)
Hazard ratio vs. nirmatrelvir–ritonavir (95% CI) ²	1.06 (0.91–1.22)	–
Clinical recovery — no. (%)		
By day 5	255 (66.4)	223 (57.6)
By day 7	331 (86.2)	316 (81.7)
By day 10	362 (94.3)	356 (92.0)
By day 14	374 (97.4)	374 (96.6)
By day 28	378 (98.4)	378 (97.7)

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Endpoints	VV116 (N=384)	Nirmatrelvir- Ritonavir (N=387)
Symptom resolution — no. (%)		
By day 5	109 (28.4)	94 (24.3)
By day 7	207 (53.9)	191 (49.4)
By day 10	283 (73.7)	276 (71.3)
By day 14	334 (87.0)	334 (86.3)
By day 28	364 (94.8)	370 (95.6)
SARS-CoV-2 clearance — no. (%)		
By day 5	186 (48.4)	183 (47.3)
By day 7	288 (75.0)	275 (71.1)
By day 10	337 (87.8)	345 (89.1)
By day 14	364 (94.8)	358 (92.5)

Notes:

1. Sustained clinical recovery was defined as the alleviation of all COVID-19-related target symptoms to a total score of 0 or 1 for the sum of each symptom (on a scale from 0 to 3, with higher scores indicating greater severity; total scores on the 11-item scale range from 0 to 33) for two consecutive days. The first day of the two-consecutive-day period was considered to be the event date.
2. Hazard ratios were calculated by means of a Cox proportional-hazards model. A hazard ratio of more than 1 suggests that participants receiving VV116 had a shorter time to sustained clinical recovery or sustained symptom resolution than those receiving nirmatrelvir-ritonavir.
3. Sustained symptom resolution was defined as a score of 0 for each of the 11 COVID-19-related target symptoms for two consecutive days.

Source: Literature review

Conclusion. This head-to-head comparison proved that early administration of oral VV116 was noninferior to nirmatrelvir-ritonavir in shortening the time to sustained clinical recovery in patients with mild-to-moderate COVID-19 who were at high risk for progression to severe disease. VV116 also had fewer safety concerns than nirmatrelvir-ritonavir. These data has been published on The New England Journal of Medicine.

Phase III Clinical Trial of VV116 for the Treatment of COVID-19

Trial Design. This is a multi-center, double-blind, randomized, placebo-controlled, Phase III study of VV116 in patients with mild-to-moderate COVID-19. This study is sponsored and conducted by a subsidiary of Junshi Biosciences in China. Enrolled patients were randomly assigned at a 1:1 ratio to receive oral VV116 (0.6g every 12 hours on day 1 and 0.3g every 12 hours on days 2 to 5) or oral placebo (on the same schedule as VV116) for five days. A total of 1369 patients were enrolled and randomly assigned to study groups (674 (50.0%) in the VV116 treatment group and 673 (50.0%) in the placebo group).

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The primary endpoint was the time to clinical symptom resolution for two consecutive days. Secondary endpoints included the time to sustained clinical symptom resolution for three days (defined as the number of days from the first dose to the first of three consecutive days when symptoms scored 0), time to sustained clinical symptom alleviation (defined as symptoms scored ≤ 1), percentage of patients who had disease progression by day 28 (consisting of COVID-19-related hospitalization of non-hospitalized patients, progression to severe COVID-19, progression to critical COVID-19, and death from any cause), percentage of patients who maintained SARS-CoV-2 negativity through days 5 to 7, and changes in SARS-CoV-2 cycle threshold value and viral load from baseline to day 5 and day 7.

Trial Status. The trial was initiated in October 2022, and was completed in March 2023. An interim analysis report of this trial was issued in January 2023, and conditional marketing approval of VV116 for the treatment of COVID-19 was granted in China based on these data.

Safety Profile. During the study, only one (0.2%) patient in the placebo group and none in the VV116 treatment group progressed to severe COVID-19. Two patients had serious adverse events, and both were in the placebo group: one had an intracranial haemorrhage and the other had a transient ischaemic attack. One patient from the placebo group had an adverse event of special interest: abnormal hepatic function. No patients in either group died or developed critical COVID-19.

Among the 1,347 patients in the safety dataset, the incidence of treatment-emergent adverse events of any grade was similar between groups (242 (35.9%) of 674 patients in the VV116 treatment group and 283 (42.1%) of 673 patients in the placebo group). 117 (17.4%) patients in the VV116 treatment group had treatment-related adverse events assessed by the investigator, as did 156 (23.2%) patients in the placebo group. The most common (incidence $\geq 5\%$ in either group) treatment-emergent adverse events included hypertriglyceridaemia (39 (5.8%) patients in the VV116 treatment group vs. 48 (7.0%) patients in the placebo group) and blood pressure increase (30 (4.5%) vs. 40 (5.9%)). Most (667 (99.0%) of 674 in the VV116 treatment group and 659 (97.9%) of 673 in the placebo group) of the treatment-emergent adverse events were Grade 1 or 2. Grade 3 or higher treatment-emergent adverse events occurred in only seven (1.0%) patients in the VV116 treatment group and 14 (2.1%) patients in the placebo group. The incidence of Grade 3 or higher treatment-related adverse events was similar between groups (three (0.4%) patients vs. two (0.3%) patients).

Among the 97 patients aged 60 years and older who received at least one dose of VV116 or placebo (49 patients in the VV116 treatment group and 48 in the placebo group), the incidences of treatment-emergent adverse events (21 (42.9%) patients in the VV116 treatment group vs 28 (58.3%) patients in the placebo group) and treatment-related adverse events (11 (22.4%) patients vs. 14 (29.2%) patients) were similar between the two groups. Treatment-emergent adverse events leading to permanent discontinuation of the investigational interventions were similar between the two groups (one (2.0%) of 49 patients in the VV116 group and one (2.1%) of 48 patients in the placebo group).

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Efficacy Profile. The results showed that 513 (79.4%) of 646 patients in the VV116 treatment group and 494 (76.0%) of 650 patients in the placebo group had sustained clinical symptom resolution for two consecutive days. The median time to sustained clinical symptom resolution for two consecutive days was 10.9 days for the VV116 treatment group and 12.9 days for the placebo group.

Similar trends favoring VV116 were observed across subgroups. Specifically, among the 93 patients aged 60 years and older, the time to sustained clinical symptom resolution was shorter in the VV116 group compared with the placebo group, consistent with the overall population. Among the 740 men, the time to sustained clinical symptom resolution was shorter in the VV116 treatment group compared with the placebo group; the same trend was observed among the 556 women. In addition, the median time to sustained clinical symptom resolution for three consecutive days was 11.9 days in the VV116 group and 13.9 days in the placebo group.

In the VV116 treatment group, a higher proportion of patients had SARS-CoV-2 negativity by day 5 than in the placebo group (41.6% vs. 31.1%). By day 5 of the study treatment, a substantial increase in the SARS-CoV-2 cycle threshold value and a more rapid decrease in viral load were observed in the VV116 treatment group compared with the placebo group.

Conclusion. VV116 produced a significant reduction in the time to sustained clinical symptom resolution compared with placebo in patients with mild-to-moderate COVID-19, with a low incidence of adverse events and a favorable safety profile. These data were published in the Lancet Infectious Diseases.

A Summary of Previous Phase I and II Clinical Trials of VV116 in Healthy Subjects and in COVID-19 Patients

In addition to the two Phase III clinical trials, VV116 has undergone several other clinical studies. For example, in 2021, VV116 completed a randomized, open-label, controlled Phase II clinical trial in Uzbekistan in patients with moderate-to-severe COVID-19. This trial was sponsored and conducted by Uzbekistan-China Pharmaceutical Science and Technology Park Co., Ltd., a subsidiary of Xinjiang Technical Institute of Physics and Chemistry, CAS. Approximately 450 participants were enrolled in the Phase II trial, which included two VV116 treatment groups (200 mg and 300 mg VV116, with both dosed orally twice daily for 5 days) and a standard treatment control group, with approximately 150 moderate-to-severe COVID-19 patients in each group. The results showed that both doses of VV116 demonstrated favorable safety profiles compared to standard treatment in treating moderate-to-severe COVID-19 patients. Additionally, VV116 exhibited good efficacy in this study. Based on these positive results, VV116 was approved in Uzbekistan in December 2021 for the treatment of moderate-to-severe COVID-19 patients.

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Previously, we also sponsored and conducted three Phase I clinical studies of VV116. Study 1 and Study 2 were randomized, double-blind, placebo-controlled, single- and multiple-dose escalation studies designed to evaluate the safety, tolerability, and PK of single and multiple oral doses of VV116 in healthy subjects. Study 3 was a randomized, open-label study aimed at investigating the food effect on the PK and safety of orally administered VV116 in healthy subjects. These studies were conducted between November 2021 and January 2022, enrolling a total of 86 eligible healthy adult subjects (38 in Study 1, 36 in Study 2, and 12 in Study 3).

The results showed that VV116 was rapidly absorbed following oral administration, with effective antiviral concentrations maintained with repeated dosing. A regular diet had no impact on VV116 exposure. In terms of safety, VV116 was well tolerated in healthy subjects. No deaths, serious adverse events, Grade 3 or higher AE, or AEs leading to discontinuation or treatment interruption were reported across the three studies. All AEs were resolved without treatment or intervention. Based on the positive results from these Phase I studies, two above mentioned Phase III clinical trials were initiated.

VV116 for the Treatment of RSV

Phase II/III Clinical Trial of VV116 Dry Suspension in Hospitalized Infants and Young Children Infected with RSV

Trial Design. This study is a randomized, double-blind, placebo-controlled Phase II/III trial of VV116 dry suspension in hospitalized infants and young children aged one to 24 months infected with RSV in China. Sponsored and conducted by us, the trial consisted of two phases: Phase II and Phase III. Phase II is a randomized, double-blind, placebo-controlled dose escalation study in approximately 60 patients aged one to 24 months. Patients will be randomized according to 3:1 ratio to receive VV116 treatment or placebo. Patients who receive treatment will receive 15mg/kg VV116 dry suspension BID consecutive for five days, 20mg/kg VV116 dry suspension BID consecutive for five days, or 20mg/kg VV116 dry suspension TID consecutively for 5 days. Phase III is a randomized, double-blind, placebo-controlled study in approximately 300 patients aged one to 24 months. Actual number of patients recruited in the Phase III study and regimens will be decided after obtaining the clinical data from the Phase II study.

The objectives of the Phase II study are to investigate the safety, efficacy, PK and antiviral activity of VV116 dry suspension in hospitalized infants and young children infected with RSV. The primary objective of the Phase III study is to evaluate the efficacy of VV116 dry suspension in hospitalized infants and young children infected with RSV. The secondary objectives of the Phase III study is to investigate the secondary efficacy index, antiviral activity, and safety of VV116 in hospitalized infants and young children infected with RSV.

Trial Status. The Phase II study was initiated in January 2024. As of the Latest Practicable Date, the trial was ongoing.

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Phase I Clinical Trial of VV116 Dry Suspension in Healthy Adult Subjects

Trial Design. This study was a randomized, open-label, Phase I trial of VV116 dry suspension in healthy adult subjects in China. Sponsored and conducted by us, the trial consisted of three parts: (1) bioavailability studies, (2) food effect studies, and (3) PK characteristic studies. A total of 38 subjects were enrolled. In the bioavailability studies, subjects were randomized into two groups. In the first group, subjects received VV116 dry suspension during the first treatment cycle and VV116 tablets during the second cycle. In the second group, subjects received VV116 tablets in the first treatment cycle and VV116 dry suspension in the second cycle. In the food effect studies, subjects were also randomized into two groups. The first group received VV116 dry suspension under fasting conditions during the first treatment cycle and 10 minutes after consuming infant formula in the second cycle. Conversely, the second group received VV116 dry suspension 10 minutes after consuming infant formula in the first treatment cycle and under fasting conditions in the second cycle. In the PK characteristic studies, subjects received 25 mg of VV116 dry suspension under fasting conditions.

The primary objectives of the study were to evaluate the bioavailability of VV116 dry suspension compared to VV116 tablets, the impact of infant formula on the PK of VV116 dry suspension, and the PK of VV116 dry suspension at different doses in healthy adult subjects. The secondary objective was to assess the safety of VV116.

Trial Status. The study commenced in July 2023, the last patient's last visit was completed in September 2023, and the study was completed in February 2024.

Results. VV116 dry suspension demonstrated similar bioavailability to VV116 tablets when administered to healthy adults under fasting conditions. Infant formula had no significant effect on bioavailability. PK studies showed that the C_{max} , AUC_{0-t} , and $AUC_{0-\infty}$ of the main metabolite of VV116 in serum increased proportionally with dose, consistent with linear pharmacokinetic characteristics.

Safety data indicated that among the 38 enrolled subjects, 11 (28.9%) experienced AEs, of which nine (23.7%) were related to the treatment drug. All reported AEs were Grade 1 or 2 and resolved completely without intervention. No SAEs, Grade 3 or higher AEs, or AEs leading to study withdrawal were reported. Overall, the safety profile was favorable.

Conclusions. VV116 dry suspension was well tolerated in healthy adults, and infant formula had no effect on the bioavailability of VV116, demonstrating potential for further investigation in infants and young children aged one to 24 months.

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Phase I Clinical Trial of VV116 Dry Suspension in Healthy Adult Subjects

Trial Design. This study was a randomized, double-blind, multiple-dosage, placebo-controlled, Phase I clinical trial of VV116 dry suspension conducted in healthy adult subjects in China. Sponsored and conducted by us, the trial comprised three groups: (1) 900 mg VV116 twice-daily treatment group (“**BID Group**”), (2) 900 mg VV116 three-times-daily treatment group (“**TID Group**”), and (3) placebo group. A total of 24 subjects were enrolled in this study, with 18 subjects receiving VV116 and six receiving a placebo. Subjects received treatment for 5.5 consecutive days, with the final dose administered on the morning of day 6.

The primary objective of this study was to evaluate the safety and tolerability of multiple doses of VV116 dry suspension. The secondary objective was to assess its PK.

Trial Status. This study was initiated in March 2024, the last patient’s last visit was completed in May 2024, and the study was completed in September 2024.

Results. Among the 24 enrolled subjects, seven (29.2%) experienced a total of ten AEs, of which four (16.7%) experienced five AEs classified as ADRs. All AEs were mild in severity and resolved completely. No deaths, SAEs, AEs of special interest, or AEs leading to study withdrawal were reported, indicating an overall favorable safety profile.

In the BID group, one subject (11.1%) experienced two ADRs. In the TID group, two subjects (22.2%) experienced two ADRs. In the placebo group, one subject (16.7%) experienced one ADR.

Additionally, PK studies indicated that after healthy adult subjects received oral administration of VV116 dry suspension at doses of 900 mg BID and 900 mg TID for 5.5 consecutive days, the median T_{max} of the primary active metabolite was similar to that observed after the first dose. The geometric mean $T_{1/2}$ was slightly prolonged compared to the first dose. C_{max} and AUC indicated mild accumulation.

Conclusions. VV116 dry suspension at doses of 900 mg BID and 900 mg TID was well tolerated in healthy adult subjects.

Clinical Development Plan

We have conducted multiple Phase I clinical trials in healthy adult subjects, confirming the safety, PK, and bioavailability of VV116 dry suspension, as well as that infant formula has no impact on the exposure of VV116. On this basis, using quantitative pharmacology modeling and simulation techniques, we constructed the PopPK and PBPK models for adults, leveraging the physicochemical properties of VV116, *in vitro* and *in vivo* pharmacodynamic and safety data, as well as adult PK data. Considering the physiological differences between infants and adults, we extrapolated the initial dosing for infants, which supports us in continuing to carry out clinical trials for infants and young children.

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As of the Latest Practicable Date, we were conducting a Phase II/III clinical trial of VV116 dry suspension in hospitalized infants and young children aged one to 24 months infected with RSV in China. We expect to conclude the Phase II stage of this trial in the second quarter of 2025 and initiate the Phase III clinical study in the third quarter of 2025. We expect to complete the registrational Phase III clinical study in the second half of 2026.

Licenses, Rights and Obligations

We were heavily involved in the development of VV116 for COVID-19 treatment. VV116 was initially co-discovered by Shanghai Institute of Materia Medica, CAS, Wuhan Institute of Virology, CAS and us. We acquired its global intellectual property rights at the PCC stage, involved in PCC determination, independently completed preclinical studies, assisted in IND submissions in China and Uzbekistan, and sponsored and conducted multiple Phase I clinical trials and a Phase III clinical trial for COVID-19 treatment in China. Furthermore, we co-own the rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 with Xinjiang Technical Institute of Physics and Chemistry, CAS in five countries in Central Asia (i.e., Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan). According to the out-licensing arrangement between Junshi Biosciences and us, we have the exclusive rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 in the Middle East, North Africa and Russia. For details, see “— Collaboration Arrangement.”

Furthermore, we have the exclusive rights to research, develop, manufacture, and commercialize VV116 for all potential indications (except for COVID-19) worldwide.

Material Communications with Competent Authorities

Our material communications with the relevant competent authorities in China on all ongoing and completed clinical trials in respect of VV116 are as follows:

- In May 2023, we received IND approval from the NMPA to conduct Phase I clinical trials of VV116 dry suspension.
- In November 2023, based on data collected from previously conducted Phase I clinical trials in healthy adult subjects in China (for both tablet and dry suspension formulations), and Phase III clinical trials in COVID-19 patients in China, we consulted with the CDE regarding the commencement of a Phase II/III clinical trial of VV116 for the treatment of hospitalized infants and young children infected with RSV. In January 2024, we received regulatory clearance from the NMPA for the commencement of this Phase II/III clinical trial, which was a “no objection” from the NMPA for the commencement of this trial according to the Announcement on the Procedures for the Review and Approval of Drug Clinical Trials published by the NMPA, in the view of our PRC Legal Adviser.

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We have not received any concerns or objections from the NMPA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VV116 FOR THE TREATMENT OF RSV SUCCESSFULLY.

Core Product — LV232 — Potential First-in-Class, 5-HTT/5-HT₃ Receptor Modulator

LV232 is a potential first-in-class, dual-target drug inhibiting 5-HTT and antagonizing 5-HT₃ receptor for the treatment of depression. The two targets of LV232 work synergistically, enhancing the antidepressant effects while reducing the severity of common gastrointestinal side effects such as nausea and vomiting, potentially leading to better safety and improved patient adherence to long-term treatment, thereby reducing the discontinuation rate. LV232 has a unique mechanism of action to address a broader range of conditions with reduced AEs, positioning it as a first-in-class treatment for depressive disorder and for improving emotional, anxiety, and pain-related comorbidities associated with depression.

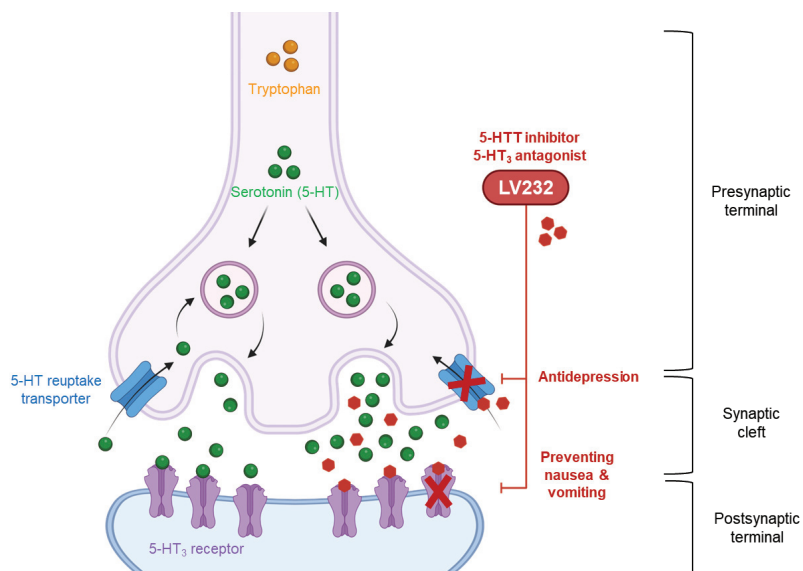
In September 2023, we received IND approval from the NMPA to conduct Phase I and Phase II clinical trials of LV232 for the treatment of depression. We initiated two Phase I clinical trials in October 2023, and trials were completed in January 2025. We have received the approval from the ethics committee for conducting a Phase II clinical trial of LV232 in depression patients in December 2024, and plan to enroll the first patient of this study in the first quarter of 2025.

Mechanism of Action

Depression is one of the most common mental disorders, characterized primarily by a significant and persistent low mood, accompanied by varying degrees of cognitive and behavioral changes. The monoamine hypothesis suggests that the reduction in the levels of monoamine neurotransmitters such as serotonin, norepinephrine, and/or dopamine in the synaptic cleft of the brain is closely related to the development and progression of depression.

LV232 has a unique mechanism of antidepressant action. It not only inhibits the serotonin transporter, increasing the concentration of 5-HT in the synaptic cleft, but also antagonizes the 5-HT₃ receptor. By antagonizing the 5-HT₃ receptor, it can reduce common side effects such as nausea and vomiting associated with selective serotonin reuptake inhibitors.

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Source: China Insights Consultancy

Market Opportunities and Competition

Depressive disorder refers to a group of mental disorder characterized by a dysphoric mood and a loss of interest and pleasure, with or without illusion, delusion, and agitation symptoms. Depression is a common and dangerous condition affecting a large population and has become a major health issue. According to GBD2021, worldwide, the number of individuals affected by these disorders was 355.3 million in 2023 and is projected to reach 399.4 million in 2035. In China, approximately 50.4 million individuals were affected in 2023, with this number expected to grow to 53.1 million in 2035. The onset of depressive disorder may drive the patients to commit suicide.

Medication therapy is the primary treatment for depressive disorder, with various drugs approved to target biochemical imbalances. First-line treatments, including escitalopram, are preferred due to their efficacy and safety in modulating 5-HT, norepinephrine, and dopamine levels. Second-line options, such as tricyclic antidepressants and tetracyclic antidepressants like amitriptyline and clomipramine, are less favored due to safety concerns and poor patient compliance. Third-line treatment include monoamine oxidase inhibitors, though restricted by dietary limitations and safety issues, are used for patients who do not respond to first- and second-line treatments. Additionally, traditional Chinese medicines are approved for mild to moderate depression, and esketamine was approved for the treatment of depression in China, yet it can be abused for its hallucinogenic properties.

There is a significant unmet medical need in the development of antidepressants. Patients with depressive disorder often struggle with poor treatment adherence and high recurrence rates, with up to 40% failing to achieve full recovery, leading to recurring symptoms. Long-term therapy is crucial for a cure, but maintaining patient compliance remains a major challenge, with interruptions often contributing to relapse. Antidepressants are also associated

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with severe side effects, such as gastrointestinal issues, migraines, hypertension, and sexual dysfunction, with 86% of patients reporting at least one side effect, 55% of which are considered bothersome. These side effects create a psychological burden, further diminishing compliance and hindering overall prognosis. Additionally, while antidepressants typically take several days to show therapeutic effects, side effects emerge much sooner, intensifying patient distress.

The antidepressant market is projected to grow steadily in the coming years. In China, the antidepressant market was valued at RMB8.1 billion in 2018, rising to RMB9.2 billion in 2023, reflecting a CAGR of 2.6% over the five-year period. It is anticipated to grow to RMB18.8 billion in 2035, at a CAGR of 6.1% from 2023 to 2035.

As of the Latest Practicable Date, 24 innovative small molecule antidepressants had been approved for marketing in China. Additionally, there were 14 innovative small molecule antidepressants under Phase II or later stage clinical development in China. LV232, an inhibitor of the 5-HTT and an antagonist of the 5-HT₃ receptor, was the only product exclusively targeting both the 5-HTT and 5-HT₃ receptor, underscoring its unique mechanism of action. For the detailed information regarding the competitive landscape of depression, see “Industry Overview — Innovative Small Molecule Drug Industry — Neuropsychiatric Drugs — Anti-depression Drugs.”

Competitive Advantages

Improved BBB Permeability

LV232 has strong BBB penetration capability. Preclinical studies of drug distribution in animal tissue indicated that LV232 has excellent BBB permeability. In one study, six cynomolgus monkeys (3 females and 3 males) were administered LV232 (20 mg/kg) via nasal gavage once daily for 28 consecutive days. On day 29, the concentration of LV232 in the brain and plasma was measured using LC-MS/MS. Based on the analytical results, the brain-to-plasma ratio of LV232 was calculated. The results showed the average concentration of LV232 in the brain was significantly higher than in the plasma, with a brain-to-plasma ratio of approximately 15.

Concentration of LV232 in Plasma and Brain, and the Brain-to-plasma Ratio

Sample	Average Concentration of LV232 (ng/ml or ng/g)	Brain-to-plasma Ratio
Plasma	5.51	1
Brain	82.45	14.96

Source: Company data

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Additionally, pharmacokinetic studies from our Phase I clinical trial showed that LV232 and its metabolites reached steady state after two to three days of continuous administration. Positron emission tomography studies also revealed that a single oral dose of LV232 achieved over 80% occupancy of the 5-HTT receptor in the brain of healthy subjects.

Improved Safety Profile

Compared to currently marketed antidepressants, LV232 is expected to reduce the severity of common gastrointestinal side effects such as nausea and vomiting, and potentially improve patient compliance. In more than 100 healthy subjects in the completed Phase I clinical trials of LV232, all adverse reactions were in Grade 1 severity and fully reversible. Given its high safety profile, LV232 is expected to have an extremely low discontinuation rate, which could significantly improve its effectiveness in treating depression.

Encouraging Efficacy Profile Based on Preclinical Studies

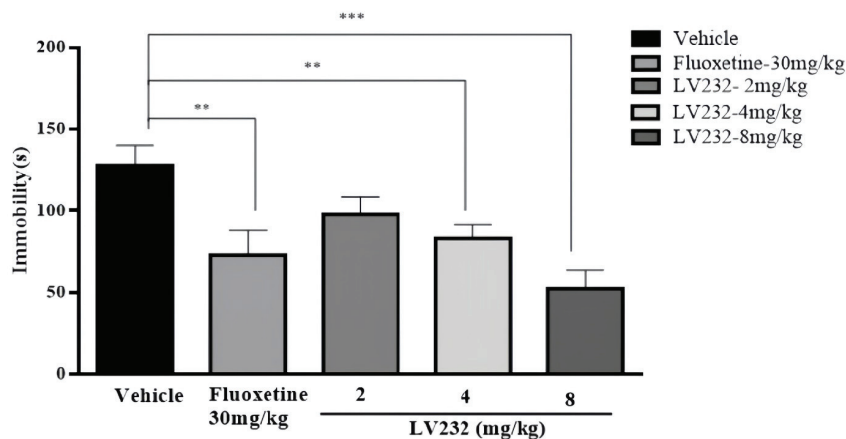
According to preclinical studies in various depression animal models, LV232 demonstrated significant antidepressant effects at lower doses compared to the positive control drug fluoxetine. Additionally, LV232 exhibited preliminary efficacy in animal models of anxiety and pain.

We investigated LV232 in an acute forced swim model. It is an animal model widely used for the screening of potential antidepressant drugs. In this model, animals are forced to swim and eventually exhibit a floating posture identified as immobility behavior, which is regarded as a sign of "behavioral despair." In the forced swim test, antidepressants cause a decrease in immobility.

The experiment utilized 8-week-old male C57BL/6J mice (n=15 per group). One hour after oral gavage administration of the drugs or solvent, the mice underwent a forced swim test. Immobility time was recorded during the last 4 minutes of a 6-minute observation period to evaluate the antidepressant efficacy of LV232. The results showed that compared to the vehicle group, the LV232 treatment groups (4 and 8 mg/kg) significantly reduced the immobility time of the mice in a dose-dependent manner. These findings indicated that LV232 exhibited significant antidepressant effects against acute depression at doses of 4 mg/kg and above.

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Forced Swim Test in C57BL/6J Mice



Note: Compared to the Vehicle group: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

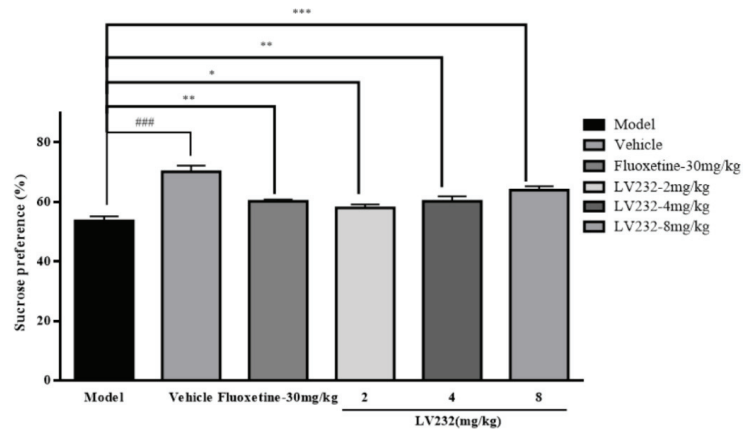
Source: Company data

Additionally, we investigated LV232 in a chronic mild stress model in mice. The chronic depression model is induced to exhibit depressive-like behavior in mice through a set of stressful factors, such as deteriorating living conditions, unpredictable shock, cold swim and reversed of day/night cycle. In a depressive state, the mice show a decrease in the consumption of sucrose solution, which is considered a sign of “anhedonia.” Treatment with antidepressants can improve anhedonia, leading to an increase in sucrose preference.

After successful model establishment, 10 to 13 mice per group were administered the drugs or solvent by gavage for four consecutive weeks. In the fourth week of administration, a sucrose preference test was conducted. The results showed that, compared to the vehicle group, the model group exhibited a significantly reduced sucrose preference, indicating a depressive state in the animals. Compared to the model group, all doses of LV232 (2, 4, and 8 mg/kg) significantly increased sucrose preference, demonstrating antidepressant effects. These findings indicated that LV232 exhibited significant antidepressant activity against chronic depression at doses as low as 2 mg/kg.

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Sucrose Preference Test After 28 Days of Administration



Note: Comparison between the drug group and the model group: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$; comparison between the model group and the vehicle group: ### $p < 0.001$.

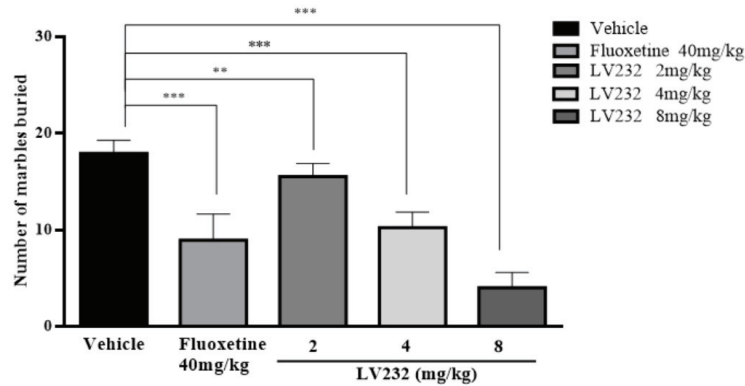
Source: Company data

In addition to its potential for treating depression, preclinical experiments have shown that LV232 may also have therapeutic effects on anxiety and pain. Specifically, we observed a notable anti-anxiety effect in mice. These experiments evaluated anxiety levels by measuring the number of marbles buried by the mice. The more anxious the mice were, the more marbles they buried. After the administration of the drug, if anxiety levels are alleviated, the number of marbles buried will decrease.

The experiment used 8-week-old male C57BL/6J mice ($n=10$ per group). One hour after oral gavage administration of the drugs or solvent, a marble-burying test was conducted, and the number of marbles buried by each group of animals was recorded. The results showed that compared to the vehicle group, LV232 (2, 4, and 8 mg/kg) significantly reduced the number of marbles buried by the mice in a dose-dependent manner. These findings indicated that LV232 exhibited significant anti-anxiety effects at a dose as low as 2 mg/kg.

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Marble Burying Test in C57BL/6J Mice



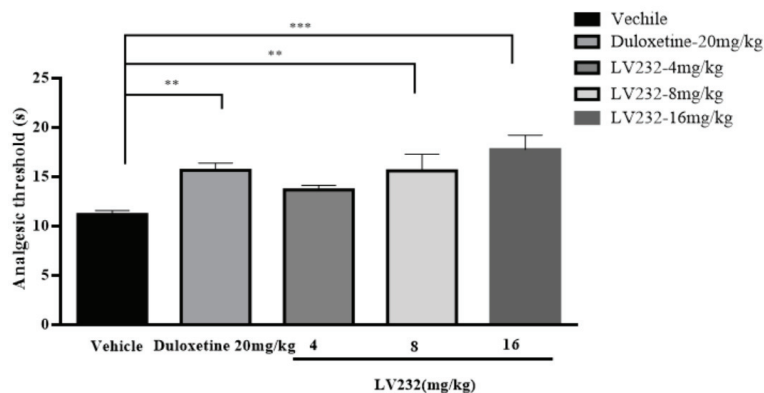
Note: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Source: Company data

The analgesic effect of LV232 was evaluated by the hot plate test. In this test, mice are placed on a heated metal plate to induce a pain response, and the time it takes for mice to lick their paws is observed to assess the analgesic effect of the drug. If the drug exhibits analgesic properties, the time to the pawlicking response (latency period) will be prolonged. A longer latency period indicates a stronger analgesic effect.

The experiment used male C57BL/6J mice (n=10 per group). Mice were administered with the drugs or solvent by oral gavage, and the hot plate test was conducted one hour after dosing. The results showed that compared to the vehicle group, LV232 (8 and 16 mg/kg) significantly increased the pain threshold of the mice in a dose-dependent manner, indicating that LV232 had an encouraging analgesic effect.

Hot Plate Test in C57BL/6J Mice



Note: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Source: Company data

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Therefore, LV232 can potentially offer significant antidepressant effects in clinical settings, with reduced gastrointestinal side effects, improved patient compliance, and better treatment outcomes for depression or comorbid conditions involving depression, anxiety, or pain.

Summary of Clinical Trial Results

Phase II Clinical Trial of LV232 in Depression Patients

Trial design. This is a randomized, double-blind, placebo- and active-controlled Phase II clinical trial designed to evaluate the efficacy and safety of LV232 capsules (20 mg, 40 mg, 60 mg, once daily) in patients with depression. All enrolled patients will be randomly assigned in a 1:1:1:1:1 ratio to one of five groups: LV232 capsules (20 mg, 40 mg and 60 mg) placebo or active control. Patients will be administered with either LV232, placebo or active control once daily for eight consecutive weeks.

The primary objective of the study is to evaluate the efficacy of different doses of LV232 capsules in patients with depression. The secondary objective is to assess the safety of LV232 capsules at various doses.

Trial Status. We have received the approval from the ethics committee in December 2024, and plan to commence patient enrollment of this study in the first quarter of 2025.

Three Phase I Clinical Trials of LV232 in Healthy Subjects

Trial Design. This was a series of Phase I clinical trials of LV232 in healthy subjects. The studies comprised three clinical trials: (1) a randomized, double-blind, placebo-controlled Phase I study of a single dose of LV232 in healthy subjects to investigate its safety, tolerability, and PK (Study 1); (2) a Phase I study of food effects and a randomized, double-blind, placebo-controlled Phase I study of multiple doses of LV232 in healthy subjects to investigate its safety, tolerability, and PK (Study 2); and (3) an open-label Phase I study of a single dose of LV232 in healthy subjects to investigate serotonin transporter occupancy in the human brain (Study 3). These clinical trials were sponsored and conducted by us in China.

In Study 1, 73 subjects were enrolled. Subjects were randomized into nine dose groups: 1mg, 2mg, 4mg, 8mg, 15mg, 25mg, 40mg, 60mg, and 90mg. For each group, approximately 6 subjects received LV232 at the respective dose, and two subjects received a placebo. Safety and PK data were evaluated within 3 days after treatment on day 1. In Study 2, 49 subjects were enrolled. 25 subjects in the multiple dose study were randomized into three dose groups: 15mg, 40mg, and 60mg. For each group, approximately six subjects received LV232 on day 1, day 3 to day 9, while 2 subjects received a placebo on these days. Safety and PK data were evaluated up to 15 days after the first treatment. 24 subjects in the food effect study were randomized into two dose groups: 20 mg and 60 mg. In each group, 12 subjects received LV232. For Study 3, approximately 20 subjects received 20mg, 40mg, and 60mg of LV232 on day 1 and 2 received 20mg active control on the same day.

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The primary objective of Study 1 was to evaluate the safety and tolerability of a single dose of LV232, as well as the safety dose range and PK. The secondary objectives of Study 1 were to evaluate the effect of a single oral dose of LV232 on the QT/QTc interval in healthy subjects, assess the changes in heart rate (HR), P-R interval, and QRS electrocardiographic parameters before and after dosing, identify the metabolites of LV232 in healthy subjects, and conduct a preliminary evaluation of the substance balance of LV232. The primary objective of Study 2 was to evaluate the safety and PK of multiple doses of LV232. The secondary objective of Study 2 was to evaluate food effect of LV232. The primary objective of Study 3 was to investigate serotonin transporter occupancy in the human brain. The secondary objective of Study 3 was to assess the safety profile after a single dose of LV232.

Trial Status. Study 1 was initiated in October 2023, the last patient's last visit was completed in November 2024, and the study was completed in January 2025. Study 2 was initiated in February 2024, the last patient's last visit was completed in December 2024, and the study was completed in January 2025. Study 3 was initiated in July 2024 and the last patient's last visit was completed in January 2025.

Results.

- **Study 1**

A total of 73 subjects were enrolled in the study and 72 subjects received a single dose of LV232 or placebo (54 subjects in the treatment group and 18 in the placebo group). In the treatment group, 16 subjects (29.6%) experienced a total of 25 TEAEs, of which 12 subjects (22.2%) experienced 19 TRAEs, defined as TEAEs associated with the drug. In the placebo group, 4 subjects (22.2%) reported a total of 4 TEAEs, with no TRAEs observed. Overall, the incidence of TEAEs was higher in the treatment group (29.6%) compared to the placebo group (22.2%), as was the incidence of TRAEs in the treatment group (22.2%), while no TRAEs were reported in the placebo group (0%).

In the study, all TEAEs were of Grade 1 severity, except for one case of Grade 4 elevated creatine phosphokinase in the 4 mg treatment group. This incident was attributed to the subject's physical activity and determined to be unrelated to LV232. All TRAEs were also Grade 1, resolved spontaneously during the study, and had no residual effects. No SAEs or TEAEs leading to withdrawal from the study were reported.

No TEAEs or TRAEs related to phototoxicity were observed during the study. However, in the 4 mg treatment group, two TEAEs related to dependency (both cases of insomnia) were reported and were deemed likely related to LV232. These events were Grade 1 in severity, resolved spontaneously during the study, and had no residual effects.

Additionally, three AEs related to arrhythmia were reported: one case of first-degree atrioventricular block and one case of sinus bradycardia occurred in the placebo group, and one case of sinus bradycardia occurred in the 15 mg treatment group. All these events were assessed as likely unrelated to LV232. They were Grade 1 in severity, resolved spontaneously during the study, and had no residual effects.

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- **Study 2**

Compared to single-dose administration, healthy subjects receiving multiple oral doses of LV232 capsules (15-60 mg) showed no significant differences in the time to peak concentration (T_{max}) for LV232, and its metabolites LV232B, LV232C, or LV232D. The half-lives of LV232B and LV232C were slightly prolonged. After multiple doses, there was no accumulation of LV232, LV232B, LV232C, LV232D, or LV232E in the body.

The safety results indicated that multiple oral doses of LV232 capsules (15-60 mg) in healthy subjects were well-tolerated. The incidence of TEAEs in the treatment group (66.7%) was lower than in the placebo group (83.3%), while the incidence of TRAEs in the treatment group (61.1%) was comparable to that of the placebo group (66.7%). All TEAEs were of Grade 1 severity, with no \geq Grade 3 TEAEs, SAEs, or TEAEs leading to study withdrawal.

Except for one subject who used glycerin for constipation, all TEAEs resolved spontaneously without residual effects. The most common TRAEs in the treatment group (incidence \geq 10%) included dizziness (5 subjects/10 events, 27.8%), nausea (5 subjects/7 events, 27.8%), diarrhea (3 subjects/4 events, 16.7%), drowsiness (2 subjects/2 events, 11.1%), and insomnia (2 subjects/2 events, 11.1%).

In addition, the food effect study demonstrated that LV232 capsules exhibited a good safety profile under fasting conditions, after a standard meal, and after a high-fat meal. Considering that the primary active substance in the body is the parent compound of LV232, it is recommended to administer LV232 capsules either in a fasting state or after a standard meal.

Conclusion. Based on the encouraging safety, tolerability, and PK results from Study 1, we proceeded with the multiple-dose Study 2. The findings from Study 2 demonstrated that LV232 capsules were well-tolerated and exhibited a favorable safety profile in healthy subjects, supporting their progression to a Phase II trial in patients with depression.

Clinical Development Plan

As of the Latest Practicable Date, we had obtained approval from the ethics committee to conduct the Phase II clinical trial of LV232 in patients with depression in China. We plan to enroll the first patient of this clinical trial in the first quarter of 2025, with the trial expected to be completed in the second half of 2026. We expect to initiate a Phase III clinical trial of short-term usage of LV232 in patients with depression in the second half of 2026.

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Licenses, Rights and Obligations

LV232 was initially discovered by Shanghai Institute of Materia Medica, CAS and Topharman Shanghai (“**LV232 Assignors**”). Our founder, Dr. Tian, has made significant contributions to the discovery of LV232 while he was working at Topharman Shanghai. After acquiring the global exclusive rights from the LV232 Assignors while LV232 was still in the early preclinical development stage, we determined and evaluated the preclinical candidate and we sponsored and completed preclinical studies and two Phase I clinical trials of LV232. For detailed information regarding the assignment agreements between the LV232 Assignors and us, see “— Collaboration Arrangement.”

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in China on all ongoing and completed clinical trials in respect of the Core Product LV232 are as follows:

- In September 2023, we received the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of LV232 for the treatment of depression. Based on data collected from the completed Phase I clinical trials, we proceeded with a Phase II clinical trial of LV232 for the treatment of depression. We received the approval from the ethics committee for conducting this trial in December 2024, and published the relevant information of the Phase II trial through the official website of the CDE in January 2025. According to our PRC Legal Adviser, this constitutes a “no objection” from the NMPA for the commencement of the Phase II trial according to the Announcement on the Procedures for the Review and Approval of Drug Clinical Trials published by the NMPA.

We have not received any concerns or objections from the NMPA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LV232 SUCCESSFULLY.

Core Product — TPN171 — Potential Best-in-Class, Highly Selective, Highly Potent PDE5 Inhibitor

TPN171 is a potential best-in-class, highly selective, highly potent PDE5 inhibitor for the treatment of for ED. PDE5 is primarily found in smooth muscle, where it specifically degrades cyclic guanosine monophosphate, reducing its concentration, which inhibits the relaxation of smooth muscle in the penile corpus cavernosum, keeping the penis in a flaccid state. PDE5 inhibitors prevent the degradation of cyclic guanosine monophosphate, thereby increasing its concentration, promoting smooth muscle relaxation, arterial dilation, and blood filling, which enhances penile erection. As a PDE5 inhibitor, TPN171 features a novel chemical structure with many advantages, including high activity, high selectivity, good safety, significant efficacy, simple structure, and ease of synthesis. Compared to competing products of the same

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target, such as sildenafil and tadalafil, TPN171 exhibits significantly lower activities for other PDEs, and better target selectivity for PDE5, making TPN171 a potential best-in-class PDE5 inhibitor with an improved safety and efficacy profile.

In January 2016, we obtained IND approval from NMPA to initiate Phase I clinical trials of TPN171 in healthy individuals. Based on the encouraging safety profile from the Phase I trials, we received IND approval from NMPA in April 2020 to conduct Phase II clinical trials of TPN171 for ED treatment. TPN171 secured the marketing approval for ED treatment in Uzbekistan in September 2022. As of the Latest Practicable Date, we have completed the registrational Phase III clinical trial of TPN171 for the treatment of ED in China, and expect to obtain the NDA approval from the NMPA around mid-2025.

Packaging of ONVITA®



Source: Company data

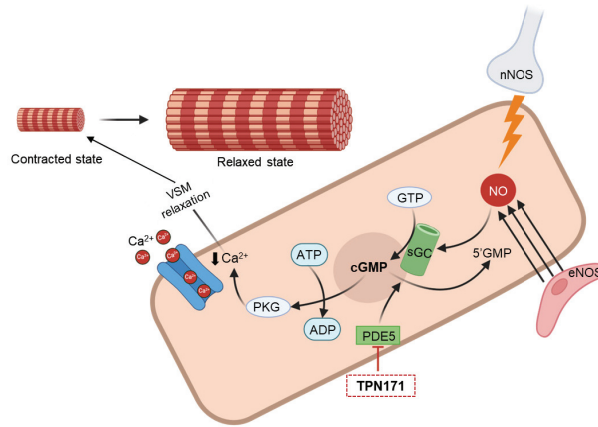
Mechanism of Action

PDE5 is predominantly found in the smooth muscle of the penile corpus cavernosum, where it specifically breaks down cyclic guanosine monophosphate, a second messenger synthesized in response to nitric oxide in the smooth muscle cells. This reduction in cyclic guanosine monophosphate concentration inhibits the relaxation of the smooth muscle in the corpus cavernosum, maintaining the penis in a flaccid state.

Drugs targeting PDE5 inhibit the enzyme's presence in the smooth muscle cells of the vessels. By inhibiting this enzyme, these drugs prevent the degradation of cyclic guanosine monophosphate by PDE5. Cyclic guanosine monophosphate can cause activation of protein kinase G, leading to relaxation of the vascular smooth muscle. Prevention of degradation of cyclic guanosine monophosphate by PDE5 leads to the accumulation of cyclic guanosine monophosphate in the vascular smooth muscle, thereby leading to dilatation of the blood vessels through phosphorylation of different downstream effector molecules. Dilatation of the penile arteries leads to a more prolonged erection. In addition, PDE5 inhibitors improve endothelial function and reduce apoptosis of vascular smooth muscle cells in the corpus cavernosum. As a selective PDE5 inhibitor, the efficacy of TPN171 in treating ED has been confirmed through registrational Phase III trials, and TPN171 secured marketing approval for ED treatment in Uzbekistan.

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A similar mechanism of action has also been shown to result in vasodilation of the pulmonary arteries, relieving pulmonary hypertension symptoms. PDE5 inhibitors also inhibit the remodeling of the pulmonary vasculature. When given to subjects suffering from heart failure, they have been known to inhibit the remodeling of the myocardium.



Source: China Insights Consultancy

Market Opportunities and Competition

For men, reproductive health issues primarily involve andrology-related disorders such as ED, PE, BPH, oligospermia, and azoospermia. ED, in particular, can lead to psychological distress, diminished self-esteem, and relationship challenges, while also potentially indicating underlying cardiovascular or metabolic issues.

PDE5 inhibitors are the first-line medication for ED treatment with a Grade A recommendation. The global market size of PDE5 inhibitors was US\$10.0 billion in 2023 and is projected to remain stable, with a slight increase to US\$10.1 billion in 2035. In China, the PDE5 inhibitor market valued at RMB9.3 billion in 2023, and is projected to reach RMB15.2 billion in 2035.

The treatment of ED involves a comprehensive approach, starting with identifying and treating any curable underlying causes, such as diabetes or hypertension. Lifestyle modifications, including improved diet, increased physical activity, and reduced alcohol or smoking, are recommended to address risk factors. Couple sexual counseling and education are provided to address emotional and relational aspects, while treatment plans are tailored to the patients' needs, preferences, and expectations through shared decision-making. A combined approach of physical therapies, like PDE5 inhibitors and vasoactive drug injections, alongside psychological support is often utilized. If treatment response is inadequate, further evaluation is necessary, with consideration for alternative therapies or combined treatments. In some cases, surgical options may be explored.

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Despite the widespread use of PDE5 inhibitors for the treatment of ED, many of the marketed PDE5 inhibitors, including sildenafil, tadalafil, and vardenafil, exhibit high inhibitory activity on PDE6 and PDE11, leading to significant adverse effects in patients. Recorded side effects include back pain, muscle pain, headache, upper abdominal discomfort, nasal congestion, flushing, vision blurred, dizziness and palpitation. Due to the safety concerns, special considerations are included in the drug specifications to warn their use in patients with renal or hepatic impairment. This highlights a significant opportunity for the development of new PDE5 inhibitors with improved safety profiles to better meet patient needs.

As of the Latest Practicable Date, the FDA approved four PDE5 inhibitors for the treatment of ED: sildenafil from Pfizer, vardenafil from Bayer, tadalafil from Eli Lilly, and avanafil from Metuchen. In China, the NMPA approved these four PDE5 inhibitors as well as aildenafil from Youcare Pharmaceutical Group for ED treatment. Sildenafil and tadalafil dominate the market, holding the majority of market share both in China and globally.

As of the Latest Practicable Date, there were seven PDE5 inhibitors under development for ED treatment in China. TPN171 stood out as one of the two product candidates that submitted NDA applications. For the detailed information regarding the competitive landscape of ED treatment, see “Industry Overview — Innovative Small Molecule Drug Industry — Reproductive Health Drugs — PDE5 Inhibitors — Competitive Landscape for ED Treatment.”

Competitive Advantages

TPN171 is a potential best-in-class, highly selective, highly potent PDE5 inhibitor. According to preclinical studies, its activity against PDE5 is an order of magnitude higher than that of sildenafil, and it exhibits significantly improved selectivity compared to other isoenzymes (including PDE1, PDE6 and PDE11). Compared to other PDE5 inhibitors available on the market, preclinical and clinical studies indicated that TPN171 offers numerous advantages, including high activity, high selectivity, good safety, significant efficacy, a simple structure, and ease of synthesis.

High Selectivity Against PDE5

All the PDE5 inhibitors share the same mechanism of action, but they differ in selectivity for PDE isozymes such as PDE1, PDE6, and PDE11, leading to specific side effects. PDE1 is associated with adverse reactions like facial flushing and cardiovascular risks, PDE6 with visual disturbances, and PDE11 with muscle soreness.

We measured the selectivity profile of TPN171 against 11 human recombinant PDEs by comparing its *in vitro* potency for PDE5 to its inhibition of other PDEs. Sildenafil and tadalafil were used as reference inhibitors, and their selectivity indexes across 11 PDEs were also evaluated in parallel. The IC₅₀ values of TPN171, sildenafil, and tadalafil toward PDE5 were 0.62, 4.31, and 2.35 nM, respectively. TPN171 showed an excellent selectivity over PDE2, 3, 4, 7, 8, 9, and 10 (>16,129-fold). Remarkably, a 1610-fold selectivity of TPN171 toward

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PDE11 was found, which was much more selective than tadalafil (9-fold). In addition, the selectivity of TPN171 over PDE1 as well as PDE6 was higher than sildenafil (5871-fold vs 190-fold to PDE1 and 32-fold vs 8-fold to PDE6). Overall, the potency and the selectivity of TPN171 over 11 PDEs were superior to those of sildenafil and tadalafil, implying that fewer side effects from the treatment with TPN171 can be anticipated.

***In Vitro* Activities and Selectivities of TPN171, Sildenafil, and Tadalafil to 11 PDE Enzymes**

PDEs	TPN171		sildenafil		tadalafil	
	IC ₅₀ (nM)	Selectivity ^a	IC ₅₀ (nM)	Selectivity ^a	IC ₅₀ (nM)	Selectivity ^a
PDE1	3640 ± 215	5871	819 ± 89	190	>10000	>4255
PDE2	>10000	>16129	>10000	>2320	>10000	>4255
PDE3	>10000	>16129	>10000	>2320	>10000	>4255
PDE4	>10000	>16129	>10000	>2320	>10000	>4255
PDE5	0.62 ± 0.13		4.31 ± 0.46		2.35 ± 0.28	
PDE6	19.8 ± 7.7	32	36.4.2 ± 1.8	8	402 ± 56	171
PDE7	>10000	>16129	>10000	>2320	>10000	>4255
PDE8	>10000	>16129	>10000	>2320	>10000	>4255
PDE9	>10000	>16129	>10000	>2320	>10000	>4255
PDE10	>10000	>16129	>10000	>2320	>10000	>4255
PDE11	998 ± 192	1610	4930 ± 1140	1144	22.1 ± 5.9	9

Note:

a. Selectivity is determined based on IC₅₀(PDEs)/IC₅₀(PDE5).

Source: Literature review

High Potency

The efficacy of pharmacological agents, including PDE5 inhibitors, in treating ED has traditionally been assessed using patient diaries and questionnaires. We evaluated the therapeutic effect of TPN171 for ED treatment based on improvements in IIEF-EF, successful penile insertion rate (SEP2), and successful erection maintenance rate (SEP3). The results from our Phase III clinical trial demonstrated that TPN171 at doses of 2.5mg, 5mg and 10mg improved all three indicators, showing significant efficacy. Specifically, in the Phase III trial, compared to the placebo group, all treatment groups exhibited at least a 2.7-point (P<0.001) improvement in the change from baseline in IIEF-EF scores, at least an 8.53% (P<0.001) increase in the percentage of “Yes” responses for SEP2, and at least a 15.21% (P<0.001) increase in the percentage of “Yes” responses for SEP3, significantly outperforming the placebo group.

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Based on a non-head-to-head comparison, data showed that TPN171 potentially demonstrated better efficacy even at a dose as low as 2.5mg, and significantly improved IIEF-EF, SEP2 and SEP3 scores. Based on a Phase III clinical trial of TPN171 for the treatment of ED in China, we observed that a 2.5mg dose of TPN171 achieved better erection functional scores, including Erectile Function domain of the IIEF-EF, SEP2, and SEP3 compared to PDE5 inhibitors with doses ranging from 2 to 80 times higher than that of TPN171.

Efficiency of Different PDE5 Inhibitors

Name	Study	Dose	IIEF-EF Changes	SEP2 Changes	SEP3 Changes
TPN171	TPN171H- E301	2.5mg	12.3	40.58%	61.91%
		5mg	12.3	42.43%	63.70%
		10mg	12.7	43.98%	65.19%
Tadalafil	Study A	20mg	6.9	26%	34%
	Study B	20mg	9.3	32%	44%
	Study C	5mg	4.0	15%	19%
		10mg	5.6	29%	32%
	Study D	5mg	5.1	18%	24%
		10mg	6.0	15%	26%
	Study E	10mg	8.1	35%	48%
		20mg	8.0	35%	50%
	Study F	20mg	6.8	27%	40%
		Study G	10mg	6.6	21%
			20mg	8.0	21%
Avanafil	Study 1	50mg	5.4	18.2%	27.8%
		100mg	8.3	27.2%	43.4%
		200mg	9.5	29.8%	44.2%
Aildenafil	Phase 3	60mg	10.11	30.58%	52.34%

Notes:

- The data for TPN171 are derived from registrational Phase III clinical trial results;
- The data for tadalafil are sourced from the package insert (brand name: Cialis, revision date: September 1, 2020);
- The data for avanafil are sourced from the package insert (STENDRA, revised: October 2022);
- The data for aildenafil are sourced from the package insert (brand name: Zydena) and the package insert disclosed by the CDE.
- The efficacy of sildenafil was evaluated using two questions from the IIEF questionnaire, which were used as the primary clinical endpoints: (1) the ability to achieve sufficient erection for sexual intercourse and (2) the ability to maintain an erection after penetration. Therefore, the efficacy data of sildenafil are not directly comparable to those of the listed PDE5 inhibitors.

Source: Company data

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Favorable Safety Profile

Multiple preclinical studies conducted in mice, rats, and dogs have demonstrated that TPN171 has a favorable safety profile. Specifically, we performed an *in vivo* study involving continuous oral gavage of solvent or TPN171 (6, 30, or 60 mg/kg) for 26 weeks in 200 rasH2 transgenic mice (25 per group and gender), analyzing animal survival and tumor development. The control group consisted of 30 rasH2 transgenic mice (15 per gender) that received a single intraperitoneal injection of carbamoylating at 1000 mg/kg on Days 1, 3, and 5, serving as a positive tumor control. The results showed that carbamoylating significantly caused mortality in rasH2 transgenic mice, with tumor-related histopathological changes observed in multiple organs. In contrast, TPN171 had no impact on animal survival and exhibited a low incidence of both tumor-related and non-tumor-related histopathological changes, with no inter-group differences. The incidence of histopathological changes were considered age-related and not associated with the test substance.

The Phase I clinical study results indicated that TPN171 demonstrated good safety and tolerability. The results also confirmed that TPN171 was safe, paving the way for Phase II clinical trials for ED. Phase III clinical study results showed that TPN171 tablets at doses of 2.5 mg, 5 mg, and 10 mg effectively treated ED. At the recommended clinical dose (5 mg), the incidence of adverse reactions such as headaches and dyspepsia was low, with no reports of muscle pain or visual disturbances. No common adverse reactions such as myalgia and abnormal vision occurred in the Phase III clinical study, which are common in marketed PDE5 inhibitors.

Based on a non-head-to-head comparison, data collected from a Phase III clinical trial in all TPN171 dose groups (2.5, 5, and 10 mg) showed that the incidence of headache, flushing, and gastrointestinal adverse events was lower than that observed with comparable PDE5 inhibitors, with no occurrence of common adverse reactions such as back pain, myalgia, or visual abnormalities. This suggests that TPN171 may offer improved safety and thus enhanced patient adherence.

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Incidence Rate of Major Adverse Reactions of Different PDE5 Inhibitors

ADR	TPN171			Sildenafil			Tadalafil		
Dose	2.5mg	5mg	10mg	25mg	50mg	100mg	5mg	10mg	20mg
Sample Size	189	190	187	312	511	506	151	394	635
Headache	2.6%	3.2%	3.7%	16%	21%	28%	11%	11%	15%
Dizziness	4.8%	5.3%	6.4%	3%	4%	3%	/	/	/
Dyspepsia	0.0%	0.5%	0.5%	3%	9%	17%	4%	8%	10%
Flushing	1.6%	3.2%	4.3%	10%	19%	18%	2%	3%	3%
Visual Abnormalities	0.0%	0.0%	0.0%	1%	2%	11%	/	/	/
Back Pain	0.0%	0.0%	0.0%	3%	4%	4%	3%	5%	6%
Myalgia	0.0%	0.0%	0.0%	2%	2%	4%	1%	4%	3%
Limb Pain	0.0%	0.0%	0.0%	/	/	/	1%	3%	3%

Abbreviation: ADR = adverse drug reaction.

Notes:

- The data for TPN171 is based on results from the registrational Phase III clinical trial;
- The data for sildenafil is sourced from the package insert (brand name: Viagra, revised date: April 23, 2024). The table lists AEs reported by $\geq 2\%$ of patients, with a higher incidence in the treatment group compared to the placebo group in the fixed-dose Phase II/III studies;
- The data for tadalafil is sourced from the package insert (brand name: Cialis, revised date: September 1, 2020). The table lists AEs reported in eight major placebo-controlled Phase III studies (including one in diabetic patients) of on-demand tadalafil tablets for ED treatment, with an incidence of $\geq 2\%$ in the tadalafil (10 or 20 mg) treatment groups, higher than that in the placebo group;
- “/” indicates that the package insert does not disclose the related data.

Source: Company data

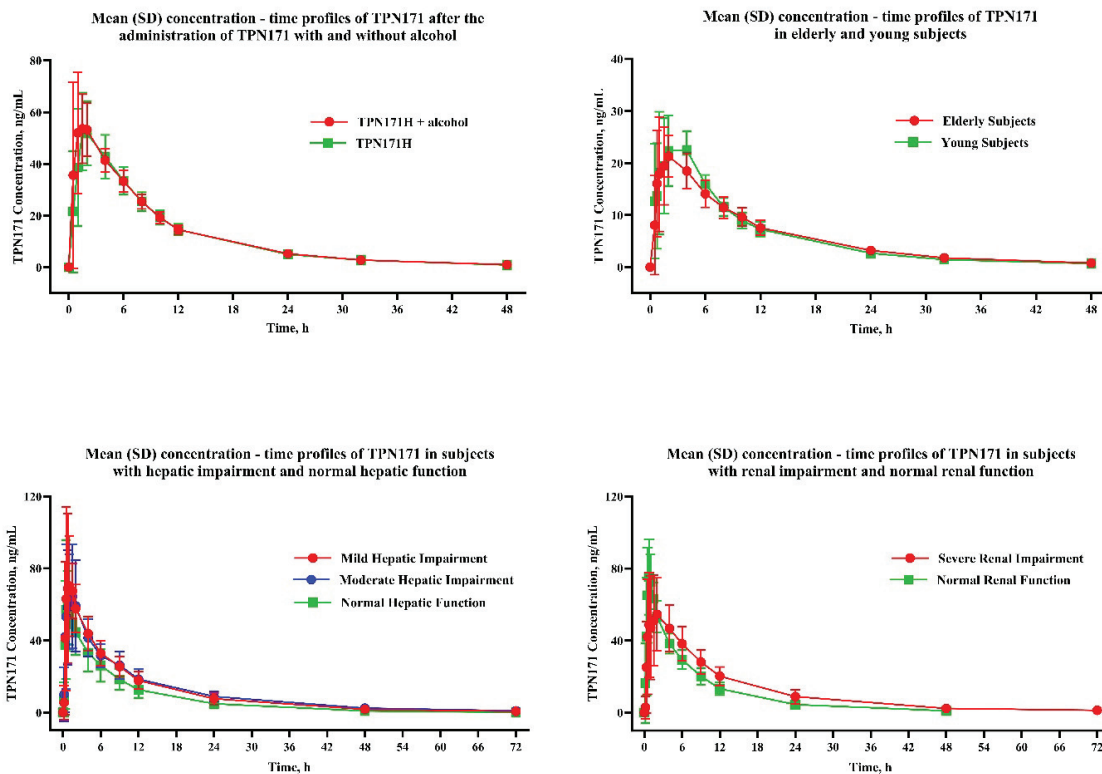
Improved Patient Compliance

In a Phase I clinical trial of TPN171 in healthy subjects, the results showed that the T_{\max} ranged from 0.5 to 1.3 hours, indicating an onset time of as short as half an hour. Meanwhile, with a half-life of 8 to 11 hours, TPN171 is expected to have a relatively long duration of action.

According to our Phase I clinical trials, TPN171 absorption was not affected by a standard meal or a high-fat diet. When taken with moderate amount of alcohol, the pharmacokinetic behavior and safety profile of TPN171 remained unaffected, making it suitable for a broader range of use cases. Phase I clinical study results in special populations showed that elderly, as well as those with mild to moderate liver impairment or mild to severe renal impairment, do not require dosage adjustments.

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Blood Concentration-Time Curve in Different Clinical Pharmacology Studies



Source: Company data

Significant Market Potential

PDE5 inhibitors are primarily recognized for their use in treating ED, but their potential extends well beyond this indication. In addition to ED, PDE5 inhibitors are approved for the treatment of PAH and BPH. These drugs also show promise for managing other conditions such as heart failure, cognitive dysfunction, and retinal diseases.

For PAH, a condition characterized by high blood pressure in the arteries of the lungs, PDE5 inhibitors work by relaxing the smooth muscles in the lung's blood vessels. This action improves blood flow, reduces pulmonary pressure, and enhances exercise capacity. Sildenafil and tadalafil are both approved for the treatment of PAH.

In the case of BPH, where prostate enlargement leads to urinary symptoms, PDE5 inhibitors help by relaxing smooth muscles in the prostate and bladder, thus improving urinary flow and alleviating symptoms. Tadalafil is specifically approved for this use, often in combination with alpha-blockers.

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Furthermore, the oral PDE5 inhibitor AR1001, developed by AriBio, has received regulatory clearance from the FDA, EMA, NMPA, MFDS and MHRA to conduct a Phase III clinical trial for the treatment of Alzheimer's disease. This highlights the potential of PDE5 inhibitors in treating cognitive diseases.

According to CIC, the global market for PDE5 inhibitors was valued at US\$10.0 billion in 2023 and is expected to remain stable, with a slight increase to US\$10.1 billion by 2035. In China, the PDE5 inhibitor market was valued at RMB9.3 billion in 2023, with projections indicating it will reach RMB15.2 billion by 2035.

Although resources are currently limited, we do not have specific plans to fully explore TPN171's potential at this time. However, future preclinical studies and clinical studies conducted by us and others could provide valuable insights and possibly lead to the identification of new therapeutic indications for TPN171.

Summary of Selected Clinical Trial Results

Below is a summary of selected Phase I, Phase II and Phase III clinical trials of TPN171. In particular, we have sponsored and completed 11 Phase I clinical trials of TPN171 in healthy subjects, two Phase II clinical trials, and one Phase III clinical trial in ED patients. We are currently conducting a Phase III clinical trial to evaluate the long-term use of TPN171 in ED patients.

Phase III Clinical Trial of Long-term Usage of TPN171 in Patients with ED

Trial Design. This is a multicenter, open-label, Phase III clinical trial designed to evaluate the long-term safety and efficacy of TPN171 in patients ED. The clinical trial is sponsored and conducted by us in China. A total of 471 evaluable patients were enrolled, with 150 patients observed for one year and 321 patients observed for six months. Each patient received 10 mg TPN171, administered 0.5 to 4 hours before sexual activity, with a maximum frequency of once per day and at least four times per month.

The primary safety evaluation criteria focused on assessing AEs and ADRs associated with TPN171. The primary efficacy evaluation criteria included assessing changes from baseline in the IIEF-EF score, the SEP2 score, and the SEP3 score after three and six months of treatment for the six-month observation period, and after three, six, nine, and 12 months for the one-year observation period.

Trial Status. The clinical trial was initiated in April 2024 and is currently ongoing. An interim analysis report has been issued based on data from 360 patients who have completed six months of treatment.

Safety Profile. Among the 360 patients who completed the six-month safety follow-up, the incidence rate of AEs was 41.9%, while the incidence rate of ADRs was 18.6%. The severity of all AEs and ADRs was classified as Grade 1 or 2, with no SAEs or SADR reported during the study. The incidence rate and severity of AEs remained consistent between the zero to three month and three to six month treatment periods.

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No patients withdrew from the study due to AEs or ADRs. Additionally, two patients (0.6%) reduced their drug dose due to AEs, while none reduced the dose due to ADRs. No patients permanently discontinued treatment due to AEs or ADRs.

Efficacy Profile. The results demonstrated that 10 mg TPN171 was effective in treating ED. The therapeutic effect of TPN171 was evaluated based on improvements in erectile function (IIEF-EF), successful penile insertion rate (SEP2), and successful erection maintenance rate (SEP3) after three months of treatment. Compared to baseline, all patients showed an increase in the percentage of “Yes” responses for all measures. After three months of treatment, 88.3% of patients achieved a normal IIEF-EF score, 96.8% reported improvements in erectile function, and 96% believed the treatment enhanced their overall sexual capability.

Conclusions. As of November 2024, a 10 mg dose of TPN171 demonstrated long-term therapeutic efficacy in treating ED with a favorable safety profile.

Registrational Phase III Clinical Trial of TPN171 in Patients with ED

Trial Design. This is a multicenter, randomized, double-blind, placebo-controlled, registrational Phase III clinical trial of TPN171 in patients with ED. The study was sponsored and conducted by us in China. 765 patients were enrolled in the study. They were randomized into four groups: 2.5mg TPN171 treatment group, 5mg TPN171 treatment group, 10mg TPN171 treatment group, and placebo group, with 190, 193, 190, and 192 patients enrolled in each group. Patients received one dose 0.5 to 4 hours before sexual activity for at least four times based on demand within one month during a 12 week period.

The primary objective of this trial was to evaluate the efficacy of TPN171 in patients with ED. The secondary objectives of this trial included safety profile, PK and PK/PD relationship.

Trial Status. This trial was initiated in December 2021, the last patient’s last visit was completed in February 2023, and the study was completed in June 2023.

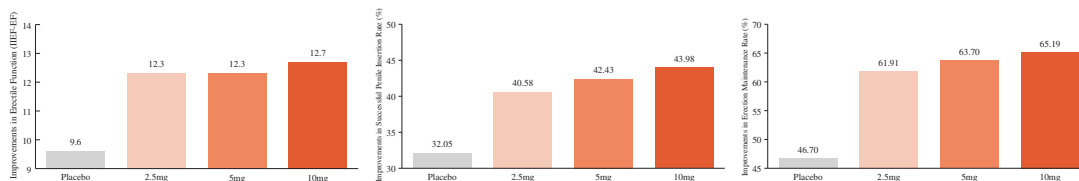
Safety Profile. Among the enrolled patients, ADRs were observed in 59 (30.9%), 72 (38.1%), 62 (32.6%), and 71 (38.0%) patients in the placebo group, 2.5mg TPN171 treatment group, 5mg TPN171 treatment group, and 10mg TPN171 treatment group, respectively. Grade 3-5 ADRs were observed in 7 (3.7%), 1 (0.5%), 2 (1.1%), and 7 (3.7%) patients in the respective groups. Serious adverse drug reactions (“**SADRs**”) occurred in 0 (0.0%), 0 (0.0%), 0 (0.0%), and 1 (0.5%) patients in the placebo group, 2.5mg TPN171, 5mg TPN171, and 10mg TPN171 treatment groups, respectively.

A total of 3 (1.6%), 0 (0.0%), 2 (1.1%), and 2 (1.1%) patients withdrew from the study due to ADRs. Additionally, 3 (1.6%), 2 (1.1%), 1 (0.5%), and 1 (0.5%) patients reduced the drug dose or suspended treatment due to ADRs, while 3 (1.6%), 0 (0.0%), 2 (1.1%), and 2 (1.1%) patients permanently discontinued treatment due to ADRs. No deaths were reported as a result of ADRs.

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Efficacy Profile. We evaluated the therapeutic effect of TPN171 for ED treatment based on improvements in erectile function (IIEF-EF), successful penile insertion rate (SEP2), and successful erection maintenance rate (SEP3). Specifically, in the Phase III trial, compared to the placebo group, all treatment groups exhibited at least a 2.7-point ($P < 0.001$) improvement in the change from baseline in IIEF-EF scores, at least an 8.53% ($P < 0.001$) increase in the percentage of “Yes” responses for SEP2, and at least a 15.21% ($P < 0.001$) increase in the percentage of “Yes” responses for SEP3, significantly outperforming the placebo group.

Efficacy of on-demand use of TPN171 Tablets



Source: Company data

Conclusion. TPN171 has proven to be an effective treatment for ED and is well tolerated by ED patients. We submitted a NDA to the NMPA in September 2023 and anticipate receiving approval around mid-2025.

Two Phase II Clinical Trials of TPN171 in ED Patients

Trial Design. Two Phase II clinical trials of TPN171 were conducted in patients with ED. Study 1 is a multicenter, randomized, double-blind, placebo-controlled, Phase II clinical trial of TPN171 in patients with ED. The study was sponsored and conducted by us in China. 255 patients were enrolled in the study. They were randomized into four groups: 5mg TPN171 treatment group, 10mg TPN171 treatment group, 20mg TPN171 treatment group, and placebo group, with approximately 64, 64, 63, and 64 patients enrolled in each group. Patients received one dose of TPN171 0.5 to 4 hours before sexual activity for at least four times within an 8 week period.

The primary objective of Study 1 was to evaluate the safety and efficacy of TPN171 in patients with ED. The secondary objectives of this trial were to explore the correlation between dosage and efficacy, as well as the correlation between dosage and safety, to provide a basis for the design of subsequent Phase III clinical studies and the determination of the dosing regimen.

Study 2 was a randomized, double-blind, placebo-controlled, Phase II clinical trial of TPN171 in patients with ED to evaluate PD. Sponsored and conducted by us in China, the study enrolled 84 patients who were randomized at 1:1 ratio into two cohorts: Cohort A: patients received placebo, 2.5mg TPN171 and 5mg TPN171 in the three treatment cycles; Cohort B: patients received placebo, 5mg TPN171 and 10mg TPN171 in the three treatment cycles.

The primary objective of Study 2 was to evaluate PD. The secondary objectives of this study were to evaluate the safety, PK, and PK/PD relationship.

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Trial Status. Study 1 was initiated in July 2020, the last patient's last visit was completed in July 2021, and the study was completed in April 2022. Study 2 was initiated in August 2022, the last patient's last visit was completed in February 2023, and the study was completed in May 2023.

Safety Profile. For Study 1, among the 245 patients evaluable for safety evaluation, treatment drug related TEAE occurred in 36.5%, 44.3%, 45.9% and 61.7% of patients enrolled in the placebo group, 5mg TPN171 treatment group, 10mg TPN171 treatment group, and 20mg TPN171 treatment group. Grade 3 or higher treatment drug related TEAE occurred in 1.6%, 0%, 3.3% and 1.7% patients in the respective groups. No treatment drug related SAE was observed in the study. One patient withdrew from the study due to TEAE, however is not related to TPN171.

For Study 2, aside from hypertriglyceridemia and hyperuricemia, which were also observed in the placebo group, the ADRs of TPN171 tablets included flushing, hot flashes, dizziness, headache, nasal congestion, nausea, and dry mouth. All ADRs were of Grade 1 severity. No treatment discontinuation or dose reduction was required, indicating that TPN171 tablets demonstrated a favorable safety profile for the treatment of ED patients.

Efficacy Profile. In Study 1, we evaluated the therapeutic effect of TPN171 for ED treatment based on improvements in erectile function (IIEF-EF), successful penile insertion rate (SEP2), and successful erection maintenance rate (SEP3). Specifically, in the Phase II trial, compared to the placebo group, all treatment groups exhibited at least improvement ($P < 0.001$) in the change from baseline in IIEF-EF scores, an increase ($P < 0.001$) in the percentage of "Yes" responses for both SEP2 and SEP3 at week 8.

In Study 2, TPN171 tablets at doses of 2.5 mg, 5 mg, and 10 mg demonstrated improvement or a trend toward improvement in erectile function in ED patients. In both Cohort A and Cohort B, the TPN171 treatment groups showed significantly longer durations of penile erection compared to the placebo group.

Conclusion. TPN171 has been shown to be an effective treatment for ED across all dosage levels. It is well tolerated by ED patients, with no treatment drug related SAEs reported.

Phase I Clinical Trials of TPN171 in Healthy Subjects

Trial Design. This was a series of Phase I studies of TPN171 in healthy subjects. 11 studies were conducted in 216 subjects to evaluate: (1) the safety and tolerability of TPN171, as well as the PK of TPN171 and its major metabolites in a single-dose regimen; (2) the safety and tolerability of TPN171, as well as food effects in a single-dose regimen; (3) the safety, tolerability, and PK of TPN171 in a multiple-dose regimen; (4) drug interactions with itraconazole and rifampin; (5) the safety, tolerability, and PK of TPN171 in the elderly in a single-dose regimen; (6) PK, mass balance, and metabolism of ¹⁴C-TPN171 in a single-dose regimen; (7) the impact of alcohol consumption on the PK of TPN171; (8) the safety and PK characteristics of TPN171 in subjects with liver impairment in a single-dose regimen; (9) the safety and PK of TPN171 in subjects with renal impairment in a single-dose regimen; (10) the effect of a single dose of TPN171 on the QT/QTc interval in healthy subjects; and (11) the effect of a single dose of TPN171 on sperm quality.

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Trial Status. This series of clinical trials was initiated between December 2017 and November 2022 and completed between March 2022 and June 2023.

Results. The results of these studies demonstrated that TPN171 was safe and well tolerated in healthy subjects, with most AEs being of Grade 1 or 2 severity. No SAEs were observed during the studies.

The results further showed that after a single oral dose of 10 mg TPN171 under fasting conditions, there was no effect on sperm motility, sperm vitality, total sperm count, sperm density, morphology, semen volume, or semen viscosity. No risk of QTc interval prolongation within the range of 10 mg to 50 mg was observed after a single oral dose of TPN171 under fasting conditions.

The PK and safety of TPN171 were not affected when taken with moderate amount of alcohol. The Phase I clinical studies in special populations indicated that elderly individuals, patients with mild to moderate liver impairment, and patients with mild to severe renal impairment can use TPN171 without the need for dose adjustment.

Conclusions. TPN171 demonstrated a strong safety profile in healthy subjects, with promising potential for medication adherence, supporting further clinical investigation.

Clinical Development Plan

As of the Latest Practicable Date, we had filed an NDA to the NMPA for TPN171 for the treatment of ED in China. We anticipate receiving approval from the NMPA around mid-2025.

Licenses, Rights and Obligations

TPN171 was initially discovered and developed for the treatment of PAH by Shanghai Institute of Materia Medica, CAS, Topharman Shanghai and Shandong Topharman (“**TPN171 Assignors**”). Our founder, Dr. Tian, has made significant contributions to the discovery of TPN171 while he was working at Topharman Shanghai. We acquired the exclusive intellectual property rights from the TPN171 Assignors to develop, manufacture and commercialize TPN171 for all possible indications on a global scale when TPN171 was under a Phase I clinical trial, intending to be developed for PAH treatment. Since then, we sponsored and completed Phase I, Phase II and Phase III clinical trials of TPN171 for the treatment of ED in China. For detailed information regarding the assignment agreements between the TPN171 Assignors and us, see “— Collaboration Arrangement.”

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Material Communications with Competent Authorities

The material communications with the relevant competent authorities in China on all ongoing and completed clinical trials in respect of the Core Product TPN171 for the treatment of ED are as follows:

- In January 2016, we obtained IND approval from NMPA to initiate Phase I clinical trials of TPN171 in healthy individuals.
- In April 2020, based on the encouraging safety profile from the Phase I trials, we received IND approval from the NMPA to conduct Phase II clinical trials of TPN171 for ED treatment.
- In September 2021, based on data collected from the previously conducted Phase I clinical trials in healthy subjects in China and Phase II clinical trials in ED patients in China we consulted with the CDE with respect to the commencement of a registrational Phase III clinical trial of TPN171 for the treatment of ED. In January 2022, we received regulatory clearance from the NMPA with respect to the commencement of a registrational Phase III clinical trial of TPN171 for the treatment of ED, which was a “no objection” from the NMPA for the commencement of this trial according to the Announcement on the Procedures for the Review and Approval of Drug Clinical Trials published by the NMPA, in the view of our PRC Legal Adviser.

We have not received any concerns or objections from the NMPA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY MARKET TPN171 FOR THE TREATMENT OF ED IN CHINA.

VV261 — RNA-Dependent RNA Polymerase Inhibitor and Broad-Spectrum Antiviral Nucleoside Prodrug

VV261 is a broad-spectrum antiviral nucleoside prodrug targeting RdRp of viruses. Once administered, it is converted into its active nucleoside triphosphate form, which inhibits the RdRp of the SFTSV, disrupting the virus’ transcription and genome replication processes to effectively treat SFTSV infection. The active form of VV261 targets the highly conserved active site of the viral polymerase, exerting its antiviral effects and reducing the likelihood of viral resistance. Preclinical studies have demonstrated that VV261 possesses potent *in vitro* and *in vivo* activity against SFTSV, with advantages such as high oral bioavailability and suitability for oral administration. Furthermore, VV261 exhibited broad-spectrum antiviral potential, showing strong inhibitory effects against a range of RNA viruses, including the novel coronaviruses, influenza virus, arenavirus, and RSV.

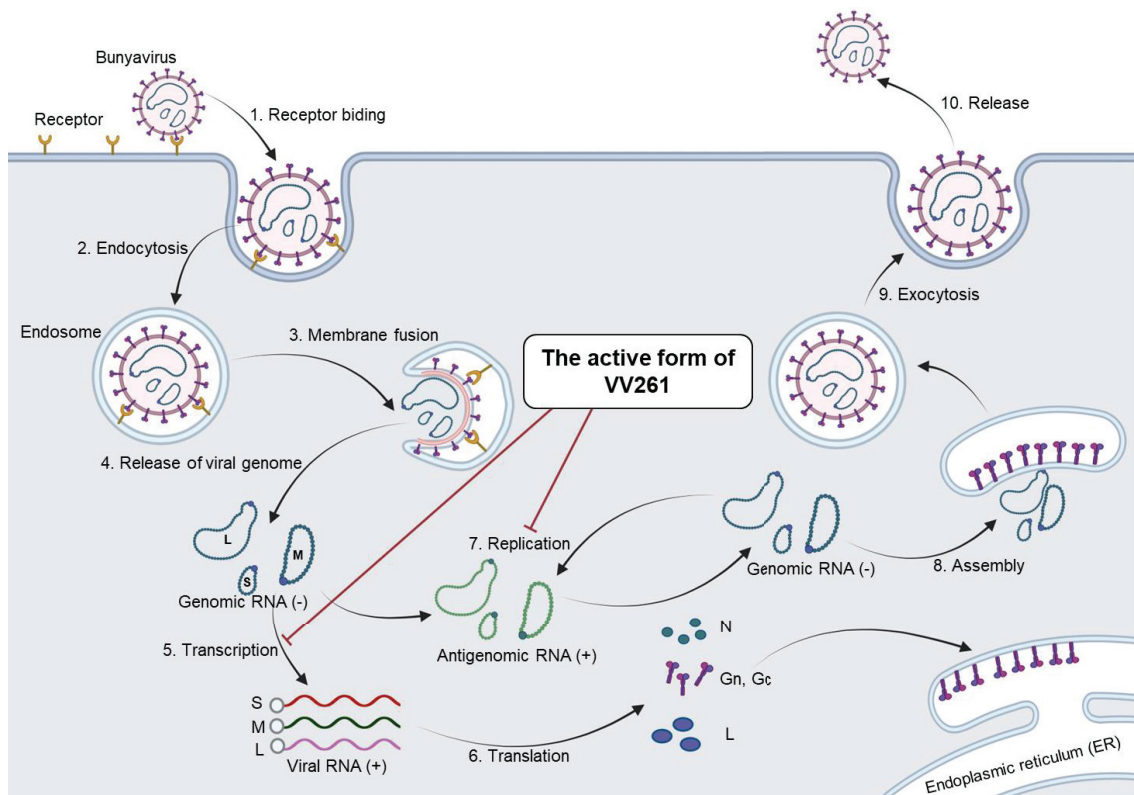
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In August 2024, we obtained the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of VV261 for the treatment of SFTSV. As of the Latest Practicable Date, VV261 was in the Phase I clinical stage.

Mechanism of Action

SFTSV belongs to the Phenuiviridae family and is a negative-sense single-stranded RNA virus. Its genome consists of three RNA segments designated large (L), medium (M), and small (S). The L segment encodes the RdRp, which plays a crucial role in the transcription and genome replication of SFTSV.

VV261 is a nucleoside prodrug that, once inside the body, is converted into its active form. This active form inhibits the RdRp of SFTSV, interfering with the virus’ transcription and replication processes, thereby achieving the goal of treating SFTSV infection.



Source: China Insights Consultancy

Market Opportunities, Competition and Competitive Advantages

SFTSV is a segmented, negative-strand RNA virus of the Bunyvirales order, belonging to the Phenuiviridae family. Its genome encodes RdRp to facilitate viral replication and transcription. The virus primarily targets human lymph nodes, leading to lymphadenopathy and necrotizing lymphadenitis, and rapidly replicates in the lymph nodes and spleen before entering

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systemic circulation, resulting in viremia. This triggers immune dysfunction, cytokine storms, endothelial damage, and, in severe cases, death due to bleeding or multiple organ failure. Reports indicate that SFTSV is associated with a high mortality rate of up to 44.7% in cases involving organ failure and central nervous system complications, with mortality rates exceeding 20% in Japan and South Korea.

According to The Lancet in 2024, the overall pooled infection rate of SFTSV was 18.94 per ten million people. SFTSV can be life-threatening, with an estimated case fatality rate of approximately 7.8%. Reports indicate that SFTSV is associated with a high mortality rate of up to 44.7% in cases involving organ failure and central nervous system complications, with mortality rates exceeding 20% in Japan and South Korea. Developing a treatment for SFTSV is crucial for society, as it addresses a pressing medical need for a disease currently lacking effective therapeutic options. The spread of SFTSV poses public health risks, often leading to societal and familial anxiety due to its potential to cause outbreaks.

Currently, general treatment of SFTSV focuses on lifestyle adjustments, including balanced nutrition, regular exercise, mental health support, and basic health monitoring. Complications treatment addresses specific medical issues arising from the condition, employing targeted therapies and specialized interventions. TCM offers a holistic alternative, utilizing herbal remedies, acupuncture, and balance-focused practices to enhance the body’s internal harmony. Nevertheless, as of the Latest Practicable Date, there was no antiviral drug for SFTSV, and existing treatments were mainly symptomatic supportive treatment and treatment for complications. Therefore, there is a significant medical need for developing antiviral drugs for SFTSV treatment.

VV261, expected to be the first and only small molecule antiviral drug for SFTSV treatment in China, is currently in the Phase I clinical stage. VV261 shows potential to overcome drug resistance mutations, exhibits an encouraging efficacy profile, and offers promising broad-spectrum applications. We are actively developing VV261 as a treatment for SFTSV with the goal of achieving expedited marketing approval. Following regulatory approval, we plan to broaden its application to address major indications, including influenza.

Summary of Clinical Trial Results

Phase I Clinical Trial of VV261 in Healthy Subjects

Trial Design. This is a randomized, double-blind, placebo-controlled Phase I dose-escalation study of VV261 in healthy subjects to evaluate its safety, tolerability, and PK. The study is sponsored and conducted by us in China. Approximately 50 subjects are expected to be enrolled. Subjects will be randomized into six groups: 10 mg, 40 mg, 100 mg, 250 mg, 500 mg, and 750 mg VV261. In each treatment group, subjects will receive either VV261 or placebo at a ratio of 3:1. A single oral dose will be administered on the first day under fasting conditions.

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The primary objective of this study is to assess the safety, tolerability, and PK of VV261 in healthy subjects. The secondary objective is to evaluate the metabolism and excretion of VV261.

Trial Status. We received the approval from the ethics committee for conducting this study in October 2024, and is currently ongoing.

Clinical Development Plan

As of the Latest Practicable Date, we were conducting a Phase I single dose-escalation study of VV261 in healthy subjects in China. Additionally, we plan to initiate a multiple dose-escalation study and a series of Phase I clinical trials to thoroughly evaluate the safety, tolerability, PK and food effects of VV261 in healthy subjects, as well as in elderly individuals, patients with mild to severe liver impairment, and patients with mild to severe renal impairment. The key clinical trials providing essential data for the initiation of a Phase II trial are anticipated to be completed in the first half of 2026. We intend to commence a Phase II clinical trial in the first half of 2027.

Licenses, Rights and Obligations

We are developing VV261 for the treatment of SFTSV. We co-discovered VV261 in collaboration with Independent Third Parties. We acquired their respective shares of rights in 2023 and we maintain the exclusive global rights to develop, manufacture and commercialize VV261.

Material Communications with Competent Authorities

We have not received any concerns or objections from the NMPA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VV261 SUCCESSFULLY.

TPN102 — Voltage-gated Sodium and Calcium Channels Inhibitor

TPN102 is a voltage-gated sodium and calcium channels inhibitor for the treatment epilepsy, targeting to suppress both generalized and focal seizures. Blocking voltage-dependent ion channels reduces the depolarization threshold of the cell membrane in the brain, making it more difficult for neurons to become excited. This mechanism helps treat epilepsy, which is characterized by neuronal depolarization. Preclinical studies of TPN102 has demonstrated significant antiepileptic efficacy in animal models and weak carbonic anhydrase II inhibitory activity in *in vitro* studies, suggesting that it can be an effective antiepileptic drug and more suitable for children with epilepsy.

We have obtained IND approval for conducting Phase I and Phase II clinical trials of TPN102 for the treatment of epilepsy from the NMPA in June 2018. As of the Latest Practicable Date, TPN102 was in the Phase I clinical stage.

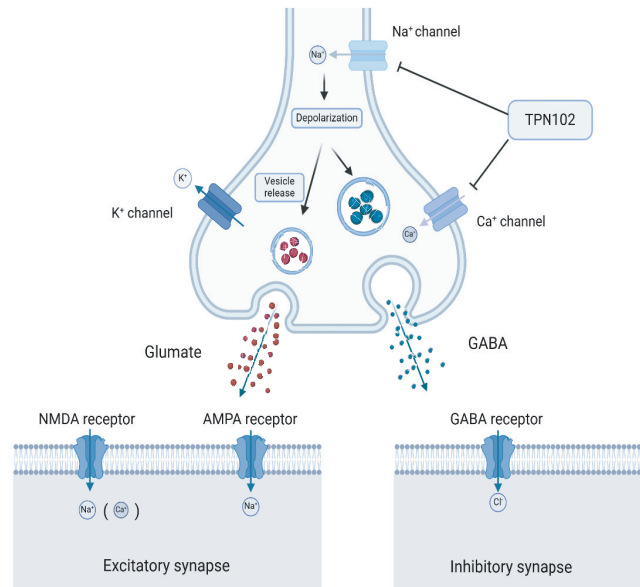
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Mechanism of Action

The internal environment of a cell is defined by the cell membrane, which maintains a negative charge, a condition known as polarization. Conversely, an increase in this polarization is termed hyperpolarization. Depolarization occurs through the flow of current outside the membrane or changes in the ionic composition of the extracellular fluid.

Stabilizing the cell membrane in the brain coordinates normal neurotransmission, making it responsive and facilitating nerve transmission and feedback. This process depends on voltage-gated ion channels, which are essential for the release of neurotransmitters from the nervous system. Inhibiting the reduction of voltage-gated ion channels can lead to an elevation of the depolarization threshold of the brain cell membrane, making it harder for neurons to become excited and thereby reducing overall brain activity, leading to a relatively calm state.

Imbalance between excitatory and inhibitory states in the nervous system can result in neuropsychiatric disorders. Epilepsy, a common neurological syndrome characterized by recurrent seizures and abnormal brain function, is a result of persistent depolarization at the neuronal level during seizures. According to preclinical studies, TPN102 demonstrated inhibitory activity on two ion channel receptors — sodium and calcium channels — at micromolar levels *in vitro*. Furthermore, TPN102 exhibited significant antiepileptic effects in various animal models of epilepsy, suggesting that both sodium and calcium channels may be the potential targets for TPN102. Based on data observed in these preclinical studies, as of the Latest Practicable Date, we believed that TPN102 targeted sodium and calcium channels, which exerts an anticonvulsant effect.



Source: China Insights Consultancy

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Market Opportunities, Competition and Competitive Advantages

Epilepsy is a chronic neurological disorder characterized by recurrent seizures, affecting millions of people globally. In 2023, approximately 64.4 million people worldwide are living with epilepsy, and this number is expected to rise to 71.7 million by 2035. In China, approximately 10.3 million people are affected by epilepsy in 2023, with projections indicating an increase to 12.6 million in 2035. Epilepsy is often caused by an imbalance between excitatory and inhibitory states in the nervous system. During an epileptic seizure, individuals may experience involuntary convulsions in a specific part of the body or throughout the entire body (focal or generalized seizures), often accompanied by loss of consciousness and urinary or fecal incontinence. Epileptic seizures are transient clinical events caused by abnormal, excessive, and synchronized neuronal discharges in the brain.

The treatment of epilepsy depends on the type of seizure and involves various first-line, add-on, and other reference treatments. Among all epilepsy patients, approximately 40% are non-convulsive (primarily manifesting as absence seizures), while the rest exhibit convulsive symptoms. Of patients with convulsive symptoms, approximately one-third have generalized seizures, and two-thirds have focal seizures. For generalized seizures, first-line treatments include valproate, lamotrigine, carbamazepine, oxcarbazepine and levetiracetam. For focal seizures, first-line treatments include carbamazepine, lamotrigine, oxcarbazepine, levetiracetam and valproate.

Current epilepsy medications face persistent challenges, including limited efficacy and significant side effects. Antiepileptic drugs, such as phenobarbital, phenytoin, carbamazepine and clonazepam, are associated with notable side effects such as drowsiness, dizziness and nausea, and require strict dosage control due to numerous drug interactions. Other antiepileptic drugs, including gabapentin, lamotrigine, levetiracetam and pregabalin, offer fewer side effects but have not substantially improved the overall efficacy or tolerability of treatment. Additionally, although 70% of epilepsy patients achieve seizure control with antiepileptic drugs, approximately 30% suffer from refractory epilepsy, where seizures remain uncontrolled despite treatment. These challenges highlight a significant unmet clinical need for the development of safer and more effective innovative therapies.

According to CIC, the antiepileptic drug market is projected to experience steady growth in the coming years. In China, the market was valued at RMB4.7 billion in 2018, rising to RMB6.0 billion in 2023, reflecting a CAGR of 4.9% over the five-year period. It is anticipated to grow to RMB9.0 billion in 2035, at a CAGR of 3.5% from 2023 to 2035.

As of the Latest Practicable Date, there were 23 innovative small molecule antiepileptic drugs approved for marketing in China. Additionally, there were six innovative small molecule antiepileptic drugs under development in China. TPN102 stood out as the only candidate targeting both voltage-gated sodium and calcium channels. For the detailed information regarding the competitive landscape of epilepsy treatment, see “Industry Overview — Innovative Small Molecule Drug Industry — Neuropsychiatric Drugs — Antiepileptic Drugs.”

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TPN102 offers competitive advantages in both safety and efficacy, positioning it as a promising antiepileptic drug for pediatric patients and those with refractory epilepsy. In preclinical studies, it was found to have a much weaker effect on carbonic anhydrase II compared to topiramate and zonisamide, suggesting that TPN102 is suitable for pediatric use. A completed single-dose escalation study in healthy subjects demonstrated no SAEs when administered with 50 to 800 mg TPN102, highlighting its favorable safety profile. Additionally, according to our preclinical studies, TPN102 showed significant therapeutic effects in various refractory epilepsy models, with efficacy outperforming first-line antiepileptic drugs.

Summary of Clinical Trial Results

Phase I Clinical Trial of TPN102 in Healthy Subjects

Trial Design. This was a randomized, double-blind, placebo-controlled, Phase I dose escalation study of a single oral dose of TPN102 in healthy subjects to evaluate its safety, tolerability, and PK. The study was sponsored and conducted by us in China. 46 subjects were enrolled in the study. Subjects were randomized into six groups: 50mg, 100mg, 200mg, 400mg, 600mg, and 800mg TPN102. In the 50 mg treatment group, 4 subjects received TPN102 while 2 received placebo. In the other treatment group, 6 subjects received TPN102, while 2 received placebo.

The primary objective of this study was to evaluate the safety, tolerability, and PK of TPN102. The secondary objective was to explore the metabolites of TPN102.

Trial Status. The study was initiated in March 2020, the last patient's last visit was completed in October 2020, and the study was completed in August 2022.

Results. No AEs led to withdrawal from the study. The vast majority of AEs were mild in severity and resolved with recovery. The adverse reactions were primarily sinus bradycardia and drowsiness. All adverse reactions were anticipated drug-related side effects. This suggests that TPN102 has good tolerability and safety in the subjects.

After a single dose of TPN102, within the dosage range of 50 to 800mg, the drug was rapidly absorbed, reaching peak blood concentration within 1 to 4 hours, with a terminal half-life of elimination ranging from 9 to 17 hours. The C_{max} and AUC of TPN102 in plasma increased with the dose, and simple linear regression analysis showed that both C_{max} and AUC followed a linear pharmacokinetic profile within the 100 to 800mg dose range.

Conclusions. TPN102 demonstrated good safety and tolerability within the 50 to 800mg dose range. These results supported the further clinical development of TPN102 in a multiple-dose study, and a starting dose of 200mg was recommended.

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Clinical Development Plan

As of the Latest Practicable Date, we had completed a Phase I single dose-escalation study of TPN102 in healthy subjects in China. Moving forward, we plan to initiate a multiple dose-escalation study and a series of Phase I clinical trials to comprehensively evaluate the safety, tolerability, PK and food effects of TPN102 in healthy subjects, as well as in elderly individuals, patients with mild to severe liver impairment, and patients with mild to severe renal impairment. The key clinical trials providing essential data for the initiation of a Phase II trial are anticipated to be completed in the second half of 2026. We intend to commence a Phase II clinical trial in the first half of 2027.

Licenses, Rights and Obligations

We are developing TPN102 for the treatment of epilepsy. We co-discovered TPN102 in collaboration with an Independent Third Party and Topharman Shanghai. We acquired their respective shares of rights in 2017 and 2019, and we maintain the exclusive global rights to develop, manufacture, and commercialize TPN102.

Material Communications with Competent Authorities

We have not received any concerns or objections from the NMPA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TPN102 SUCCESSFULLY.

VV119 — Multi-target Serotonin-Dopamine Activity Modulator

VV119 is an internally discovered, multi-target serotonin-dopamine activity modulator for the treatment of psychiatric disorders, especially schizophrenia. As a prodrug, VV119 and its major active metabolite can act through a combination of antagonistic activity at the D₃ receptor, partial agonistic activity at the D₂ receptor, partial agonistic activity at the 5-HT_{1A} receptor, antagonistic activity at the 5-HT_{2A} receptor, and inhibitory activity on the 5-HT transporter. VV119 adopted a multi-target strategy and acts as a serotonin-dopamine activity modulator. It has a long half-life and holds potential for development as a long-acting formulation. Preclinical data have shown that VV119 may improve positive symptoms, negative symptoms, and cognitive function in schizophrenia while also reducing the risk of extrapyramidal side effects. These potential clinical benefits position VV119 as an enhanced treatment option, promoting better patient adherence.

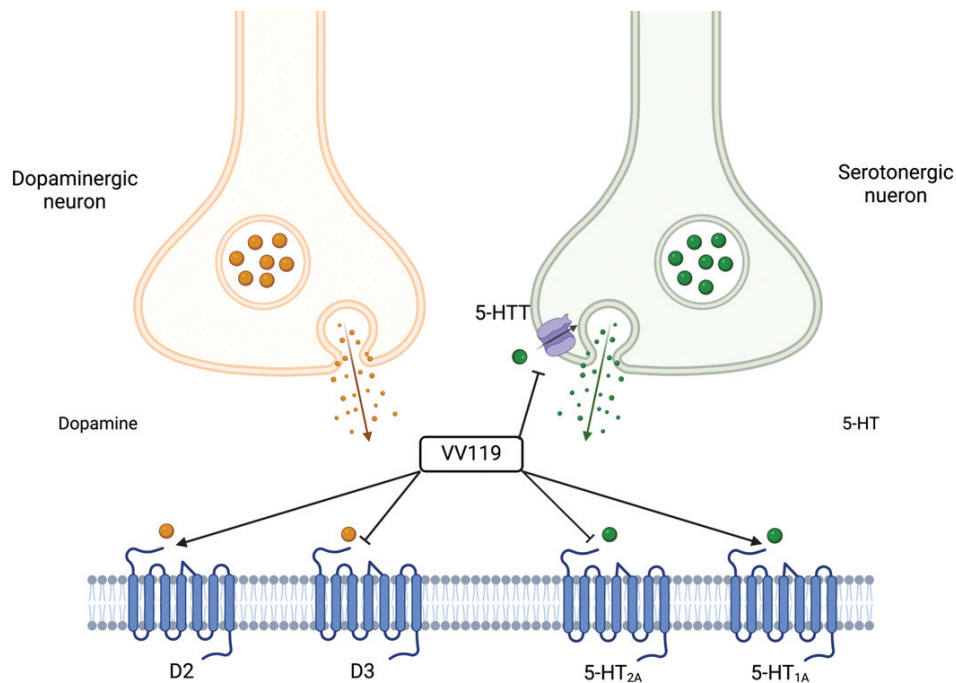
We received IND approval for conducting Phase I and Phase II clinical trials of VV119 for the treatment of schizophrenia from the NMPA in September 2023. As of the Latest Practicable Date, VV119 was in the Phase I clinical stage.

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Mechanism of Action

Schizophrenia is a serious mental health condition that affects how people think, feel and behave. It may result in a mix of hallucinations, delusions, and disorganized thinking and behavior. Hallucinations involve seeing things or hearing voices that are not observed by others. The pathogenesis of schizophrenia is complex, with hypothesis suggesting that the cause can be related to dopamine hyperfunction, serotonin dysfunction, and glutamate receptor disturbances.

VV119 is a prodrug that is converted into its active form within the body. The active compound partially activates dopamine D₂ receptor, thereby preventing both excessive activation and complete blockade of these receptors. In addition, it antagonizes dopamine D₃ receptor to enhance cognitive function, partially activates 5-HT_{1A} receptor to alleviate negative symptoms and cognitive impairments associated with schizophrenia, and blocks 5-HT_{2A} receptor to improve negative symptoms of the disorder.



Source: China Insights Consultancy

Market Opportunities, Competition and Competitive Advantages

Schizophrenia is a severe mental disorder characterized by disturbances in perception, emotion, cognition, and behavior, typically emerging in young adulthood and often resulting in lifelong suffering. In 2023, schizophrenia affected 24.6 million people globally, with the number expected to reach 30.3 million in 2035. In China, the condition affected 15.2 million people in 2023, with projections indicating 18.0 million in 2035.

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Antipsychotic drugs are the preferred treatment for schizophrenia. They can be generally divided into conventional and atypical drugs. Conventional antipsychotic drugs primarily target D₂ receptor, while atypical antipsychotic drugs target multiple receptors, including dopamine and 5-HT, to offer a broader range of targets and improved efficacy in modulating neurotransmitter balances. Atypical antipsychotic drugs are now considered first-line treatments due to their better efficacy and safety profiles. In addition to medication, electroconvulsive therapy and modified electroconvulsive therapy are also recommended treatments, particularly during the acute phase. Psychological and social interventions are also recommended to help patients reintegrate into society and regain social skills.

Current treatments for schizophrenia primarily rely on antipsychotic medications, which effectively alleviate positive symptoms (such as hallucinations and delusions) but have limited impact on negative symptoms (such as social withdrawal and emotional blunting) and cognitive impairments. Moreover, long-term use of these medications carries risks of severe side effects, such as metabolic issues and movement disorders, resulting in poor patient adherence and a higher risk of relapse. Consequently, there is an urgent need for safer and more effective therapies that comprehensively address multiple dimensions of the disorder.

The antipsychotic drug market is projected to experience steady growth in the coming years. According to CIC, in China, the market was valued at RMB8.2 billion in 2023 and is anticipated to grow to RMB13.6 billion in 2035, at a CAGR of 4.4% from 2023 to 2035.

As of the Latest Practicable Date, 22 innovative small molecule antipsychotic drugs have been approved for marketing in China. Additionally, there were 16 innovative small molecule antipsychotic drugs under clinical development in China. For the detailed information regarding the competitive landscape of schizophrenia treatment, see “Industry Overview — Innovative Small Molecule Drug Industry — Neuropsychiatric Drugs — Antipsychotic Drugs.”

Based on our preclinical studies, VV119 holds potential for development as a long-acting formulation. It has demonstrated the ability to improve both the negative and positive symptoms of schizophrenia, as well as cognitive function, while avoiding side effects such as dizziness and reduced body temperature. These benefits contribute to improved patient adherence to treatment, positioning VV119 as a competitive drug candidate for the treatment of schizophrenia.

Summary of Clinical Trial Results

Phase I Clinical Trial of VV119 in Healthy Subjects and Adult Patients with Schizophrenia

Trial Design. This is a randomized, double-blind, VV119 plus placebo-controlled, Phase I dose escalation study of VV119 in healthy subjects and adult patients with schizophrenia to evaluate the safety, tolerability, and PK. The study is sponsored and conducted by us in China. Approximately 32 subjects are expected to be enrolled in the study. They will be randomly assigned at a 3:1 ratio to receive VV119 or a combination of VV119 and placebo. Subjects in the treatment groups will receive 0.5mg, 1mg, 2mg, or 4mg VV119 treatment group. The study is designed to be conducted in two phases: the first phase will be conducted in healthy subjects, and the second phase will be conducted in schizophrenia patients. During the first phase, subjects will receive a single oral dose of VV119 or placebo every day for 14 consecutive days under fasting conditions. During the second phase, adult patients will receive VV119 or a combination of VV119 and placebo every day for 28 consecutive days under fasting conditions.

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The primary objective of the study is to evaluate the safety and tolerability of VV119. The secondary objectives of the study include evaluating the PK of VV119, and assessing the preliminary efficacy of VV119 in adult patients with schizophrenia.

Trial Status. This study was initiated in July 2024, respectively, and is currently ongoing.

Clinical Development Plan

As of the Latest Practicable Date, we were currently conducting Phase I single and multiple dose-escalation studies of VV119 in healthy subjects and adult patients with schizophrenia in China. Additionally, we plan to initiate a series of Phase I clinical trials to comprehensively evaluate the safety, tolerability, PK and food effects of VV119 in healthy subjects, as well as in elderly individuals, and patients with mild to severe liver impairment or mild to severe renal impairment. The key clinical trials providing critical data for the initiation of a Phase II trial are anticipated to be completed in the fourth quarter of 2025. We intend to commence a Phase II clinical trial in the first half of 2026.

Licenses, Rights and Obligations

As VV119 is internally discovered and developed by us, we maintain the exclusive global rights to develop, manufacture and commercialize VV119.

Material Communications with Competent Authorities

We have not received any concerns or objections from the NMPA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VV119 SUCCESSFULLY.

Other Innovative Product Candidates in IND-Enabling or Preclinical Stage

Our selected innovative preclinical product candidates also mainly focusing on the three therapeutic areas, i.e. viral infection, neuropsychiatry, as well as reproductive health.

Viral Infection Sector

VV207 is an orally administered nucleoside prodrug with a novel structure, exhibiting broad-spectrum antiviral activity against DNA viruses, including adenovirus, poxvirus, herpesvirus, and hepatitis B virus, with an EC₅₀ in the nanomolar range. Adenovirus is a double-stranded DNA virus that is widely distributed in mammals and birds. It is highly infectious, spreads easily, and can cause a range of diseases, such as adenoviral pneumonia, acute conjunctivitis, gastroenteritis, and cystitis. Currently, no effective or targeted vaccines or therapeutic agents are approved for adenovirus infections. Treatment primarily focuses on

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symptomatic relief and preventing secondary infections, but these approaches often yield unsatisfactory results. As such, there is an urgent global need for antiviral drugs with a well-defined mechanism of action, significant therapeutic efficacy, and high barrier to resistance.

We co-discovered VV207 with Independent Third Party partners and jointly own the global rights to research, development, manufacture and commercialize VV207. As of the Latest Practicable Date, VV207 was under preclinical studies. We expect to submit an IND application to the NMPA in the second half of 2026.

Neuropsychiatry Sector

VV147 is designed to provide rapid therapeutic effects in the treatment of depressive disorder. Depression is a mood disorder marked by high incidence, frequent relapses, and significant disability, which has a profound impact on public health. Despite advances in treatment, clinical management of depression still faces several challenges. Notably, many commonly prescribed antidepressants have a delayed onset of action, typically requiring 2 to 4 weeks of administration before showing noticeable effects. This delay often results in higher rates of treatment discontinuation and lower patient adherence, which severely impedes the successful management of depression. While esketamine, an adjunctive treatment for depression, offers a rapid onset, its risk for abuse limits its clinical use. Preclinical studies have shown that a single oral dose of VV147 exhibited significant antidepressant-like effects in various chronic depression models, including chronic unpredictable mild stress and chronic social defeat stress, with promising rapid onset potential. Additionally, VV147 demonstrated no addictive-like effects in the conditioned place preference model, suggesting improved accessibility compared to esketamine.

We co-discovered VV147 with an Independent Third Party partner and jointly own the global rights to research, development, manufacture and commercialize VV147. As of the Latest Practicable Date, VV147 was under preclinical studies. We expect to submit an IND application to the NMPA in the first half of 2026.

Reproductive Health Sector

VV913 is a small molecule with a novel structure designed for the treatment of PE, a common male sexual dysfunction that can significantly affect patients' quality of life. Pharmacological treatment is the first-line approach for PE, with dapoxetine being the only approved oral medication. However, dapoxetine is associated with side effects such as nausea, dizziness, and reduced libido, highlighting the urgent need for the development of faster-acting and safer alternatives. Preclinical *in vivo* studies have indicated that VV913 is effective in treating PE and offers the benefit of on-demand dosing. In the preclinical studies, it demonstrated significant efficacy in a rat model of PE, where a single dose notably extended ejaculation latency and reduced ejaculation frequency, showing promise for on-demand use. Furthermore, in balance beam and sexual arousal tests, compared to dapoxetine, VV913 demonstrated favorable safety with a much lower risk of side effects, such as dizziness and decreased libido, than those of dapoxetine in male rats.

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We co-discovered VV913 with Independent Third Party partners. We acquired their respective shares of rights in 2023 and we maintain the exclusive global rights to research, development, manufacture and commercialize VV913. As of the Latest Practicable Date, VV913 was under preclinical studies. We expect to submit an IND application to the NMPA by the end of 2025.

Non-Pipeline Program

Due to the fact that PDE5 inhibitors can inhibit pulmonary vasculature remodeling, we have been developing TPN171 for the treatment of PAH. PAH is a life-threatening, progressive disease affecting the pulmonary vasculature, often associated with complex cardiovascular and respiratory conditions. Preclinical studies have shown that oral administration of TPN171 significantly reduced mean pulmonary artery pressure in rats with monocrotaline-induced PAH, with an effective dose much lower than that of sildenafil. Furthermore, TPN171 was proven safe and well-tolerated at a dose of 10 mg in Phase I clinical trials. However, given the limited number of PAH patients and the limited resources available, we have decided to prioritize the development of TPN171 for the treatment of ED. As of the Latest Practicable Date, TPN171 was undergoing a Phase II clinical trial for PAH, with no current plans for further clinical development in this indication.

GENERIC DRUG PIPELINE

To complement our innovative product pipeline and mitigate the inherent risks associated with the development of innovative therapies, while ensuring sustainable growth, we are also advancing a portfolio of generic products. Our generic drug pipeline includes dapoxetine, rebamipide, brexpiprazole, and letermovir. We have already received ANDA approval for dapoxetine and rebamipide from the NMPA and have submitted the ANDA application for brexpiprazole in China. As of the Latest Practicable Date, letermovir was under laboratory development in China. The following chart illustrates our generic product pipeline and summarizes the status of our approved products, as well as product candidates under development as of the Latest Practicable Date:

	Pipeline Product	Classification	Indications (Lines of Treatment)	Laboratorial Development	Process Validation	IND-Enabling	Bioequivalence Trial	ANDA	Upcoming Milestone	
Generic Product Pipeline	Dapoxetine	4	Premature Ejaculation	[Progress bar: 100%]						-
	Rebamipide	4	Gastric Ulcers, Gastric Mucosal Lesions, Acute Gastritis and Acute Exacerbation of Chronic Gastritis	[Progress bar: 100%]						-
	Brexpiprazole	4	Major Depressive Disorder	[Progress bar: ~80%]						Marketing Authorization Obtained in Q4 2025
	Letermovir	4	Prophylaxis of Cytomegalovirus Infection and Disease in Adult CMV-Seropositive Recipients (R+) of an Allogeneic Hematopoietic Stem Cell Transplant	[Progress bar: ~20%]						Submission of ANDA application to NMPA in Q4 2025

Source: Company data

- Dapoxetine** is a selective serotonin reuptake inhibitor used in the treatment of PE. The brand-name drug, developed by Eli Lilly, received marketing approval from the NMPA in December 2010. With a relatively short metabolic cycle and high adaptability, selective serotonin reuptake inhibitors (SSRIs), including dapoxetine have become a gold standard in the PE field according to CIC. In October 2023, we received approval for the finished dosage form, dapoxetine hydrochloride tablets (30mg).

BUSINESS

- **Rebamipide** is an endogenous mucosal protective agent for the treatment of various gastrointestinal diseases. It works by inducing the expression of cyclooxygenase-2 in the gastric mucosa, which increases the synthesis of prostaglandin E2 in the gastric mucosa. It also enhances gastric mucosal blood flow and mucus secretion, promotes the expression of epithelial growth factor genes in the gastric mucosa, thereby preventing the occurrence of ulcers and promoting ulcer healing. The brand-name drug was developed by Otsuka Pharmaceutical Co., Ltd. for the treatment of gastric ulcers, gastric mucosal lesions, acute gastritis, and the acute exacerbation of chronic gastritis. It was approved for marketing by the PMDA in December 1990. We have obtained marketing approval of this product from the NMPA in December 2024.
- **Brexipiprazole** is a 5-HT/DA activity modulator that exhibits partial agonist activity at the 5-HT_{1A} and D₂ receptors, along with an antagonistic effect at the 5-HT_{2A} receptor. It is indicated for the treatment of schizophrenia in adult patients. The brand-name drug was developed by Otsuka Pharmaceutical Co., Ltd. for the treatment of adult schizophrenia and as an adjunctive treatment for major depressive disorder. Approved by the FDA in July 2015, brexpiprazole is regarded as one of the most promising therapies for schizophrenia. In July 2024, we submitted an ANDA for marketing approval to the NMPA, with approval expected in the second half of 2025. As of the Latest Practicable Date, we have not received any concerns or objections from the NMPA regarding our clinical development plans.
- **Letermovir** is a novel inhibitor that targets the CMV DNA terminase, blocking its ability to cleave newly synthesized CMV DNA into individual viral genomes and package them into empty viral capsids, thereby inhibiting viral replication. Developed by Merck Sharp & Dohme B.V., the brand-name drug is indicated for the prevention of CMV infection and disease in adult CMV-seropositive recipients of allogeneic hematopoietic stem cell transplants. It is also used for preventing CMV disease in high-risk adult kidney transplant recipients. Letermovir received FDA marketing approval in November 2017, followed by marketing approval from the EMA and PMDA in 2018, and NMPA marketing approval in December 2021. We are currently conducting laboratory-scale testing, with pilot-scale production expected to begin in the first quarter of 2025. As of the Latest Practicable Date, we have not received any concerns or objections from the NMPA regarding our clinical development plans.

BUSINESS

COLLABORATION ARRANGEMENT

VV116 Agreements

Starting in October 2020, we entered into a series of agreements, including a technology transfer agreement and supplemental agreements (the “**VV116 Assignment Agreements**”), with Shanghai Institute of Materia Medica, CAS, and Wuhan Institute of Virology, CAS (the “**VV116 Assignors**”), acquiring exclusive intellectual property rights related to VV116 controlled by the VV116 Assignors on a global scale. The VV116 Assignors are Independent Third Parties. We became acquainted with them through our founder Dr. Shen, who is a researcher, group leader, and doctoral supervisor at Shanghai Institute of Materia Medica, CAS.

Starting in September 2021, we entered into a series of agreements (the “**VV116 Out-Licensing Agreements**”) with Junshi Biosciences, out-licensing the acquired exclusive rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 on a global scale, except for four regions or countries: five countries in Central Asia (i.e., Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (i.e., Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (i.e., Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan), and Russia (the “**Company Regions**”). Junshi Biosciences is an Independent Third Party. We became acquainted with Junshi Biosciences through our shared goal of developing a therapeutic product for the treatment of COVID-19.

In March 2022, we entered into an agreement with Xinjiang Technical Institute of Physics and Chemistry, CAS (the “**VV116 Co-Developer**”) to co-develop VV116 for the treatment of COVID-19 in the five countries in Central Asia (the “**VV116 Collaboration Agreement**”). The VV116 Co-Developer is an Independent Third Party. We became acquainted with the VV116 Co-Developer due to the shared goal of developing and commercializing a COVID-19 treatment drug in Uzbekistan in response to the PRC government’s Belt and Road Initiative.

BUSINESS

The salient terms of the three groups of agreements (collectively, the “**VV116 Agreements**”) are summarized below:

**Rights Transferred/License
Granted (if applicable)**

Upon the acquisition of global exclusive rights to research, develop, manufacture, and commercialize VV116 for all possible indications from the VV116 Assignors, we out-licensed our exclusive rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 to Junshi Biosciences in certain countries and regions, with the right to transfer or sublicense its rights upon our consent, and transferred to the VV116 Co-Developer undivided one-half interest in our exclusive rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 in the five countries in Central Asia. As a result:

- We have the exclusive rights to research, develop, manufacture, and commercialize VV116 for all potential indications (except for COVID-19) worldwide. We also have the exclusive rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 in the Middle East, North Africa and Russia. Furthermore, we co-own the rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 with the VV116 Co-Developer in the five countries in Central Asia.
- Junshi Biosciences holds the exclusive rights to research, develop, manufacture, and commercialize VV116 for the treatment of COVID-19 worldwide, except for the Company Regions (the “**Junshi Biosciences Regions**”).

Allocation of Responsibilities

- Pursuant to the VV116 Assignment Agreements, we are generally responsible for advancing the research, development, manufacturing, and commercialization of VV116 on a global scale. The VV116 Assignors are obligated to provide technical support to assist in the clinical development of VV116. Any fees incurred as a result of providing such technical support will be borne by us. Additionally, the VV116 Assignors are obligated to assist with patent procedures, including patent applications, registrations, usage, and enforcement.

BUSINESS

- Pursuant to the VV116 Out-Licensing Agreements, Junshi Biosciences is obligated to develop and commercialize VV116 for the treatment of COVID-19 in the Junshi Biosciences Regions, with associated costs borne by them. We are obligated to complete GLP safety analysis studies for FDA IND application and to assist Junshi Biosciences in the subsequent clinical development. We are also obligated to provide necessary technical assistance to Junshi Biosciences. The VV116 Assignors and the VV116 Co-Developer have the right to be informed of the clinical development progress in order to provide necessary assistance in the development of VV116.
- Pursuant to the VV116 Collaboration Agreement, both the VV116 Co-Developer and we are obligated to advance and fund the clinical development of VV116 in the five countries in Central Asia. We are responsible for providing relevant research results, supplying the API of VV116 and the sales and distribution of VV116 in Uzbekistan. The VV116 Co-Developer is responsible for handling regulatory affairs and manufacturing of VV116, and will serve as the marketing authorization holder in Uzbekistan. We are responsible for ensuring the quality of the API, while the VV116 Co-Developer is responsible for the quality of the VV116 formulation product. If one party fails to fulfill its obligations, the other party is obligated to continue performing the VV116 Collaboration Agreement.

Payments

- We have fully paid the VV116 Assignors certain assignment fees in accordance with the terms of the VV116 Assignment Agreements. We are also obligated to pay the VV116 Assignors a low single-digit royalty based on the annual sales revenue of VV116 on a global scale.

BUSINESS

- Pursuant to the VV116 Out-Licensing Agreements, upon achieving the agreed research and commercialization milestone events in the Junshi Biosciences Regions, Junshi Biosciences is obligated to pay us respective milestone payments. It is also obligated to pay, for a period of ten years from the launch date of VV116 in a specific country or region, a low-teen royalty based on the annual sales revenue of VV116 in the Junshi Biosciences Regions, or a mid-twenties percentage of the gross profits generated from sales of VV116 in the Junshi Biosciences Regions.
- Pursuant to the VV116 Collaboration Agreements, the gross profits generated from the sales of the VV116 formulation product will be equally shared between the parties. If one party relinquishes part or all of its obligations due to objective reasons, the other party has the right to assume those obligations to ensure the advancement of the project. In such cases, the profit allocation will either be solely enjoyed by the performing party or distributed based on each party's respective contribution.
- Pursuant to the VV116 Assignment Agreements, for all patent rights transferred under the VV116 Assignment Agreements, the VV116 Assignors reserve the right to be named as co-applicants, but forfeit any other rights under applicable laws and regulations in China, except for the rights to receive payments pursuant to the VV116 Assignment Agreements.
- Pursuant to the VV116 Out-Licensing Agreements, for all new inventions, we retain sole ownership of the intellectual property rights in the Company Regions, while Junshi Biosciences retains sole ownership of the intellectual property rights in the Junshi Biosciences Regions, no matter who create the inventions. In both cases, the VV116 Assignors will be named as co-applicants and forfeit any other rights under applicable laws and regulations.

Intellectual Property Arrangements

BUSINESS

Term and Termination

- The terms of VV116 Assignment Agreements are 20 years, unless there is an earlier termination mutually agreed upon by the parties.
- Pursuant to the VV116 Assignment Agreements and the VV116 Out-Licensing Agreements, the royalty payment obligations will be terminated upon the later of (i) 10 years since the launch date of a product under this project in every country or region, and (ii) when the legal protection term of a patent that protects the product expires in the respective country or region.
- The VV116 Assignment Agreements and the VV116 Out-Licensing Agreements may be terminated in the event of an incurable material breach that renders the performance of the relevant agreement impossible.
- The VV116 Assignment Agreements can be terminated in the event of (1) force majeure, (2) the discontinuation of the clinical studies due to technical difficulties that cannot be overcome, or (3) material defects in the technology that cannot be cured within two years by the VV116 Assignors. In addition, we have the right to voluntarily terminate the VV116 Assignment Agreements. If the VV116 Assignment Agreements are terminated, the rights assigned by the VV116 Assignors shall revert to them.

According to CIC, the terms of the VV116 Agreements are in line with industry norms.

BUSINESS

LV232 Agreements

In 2021 and 2023, Nantong Hefeng entered into a transfer agreement and a supplemental agreement (the “**LV232 Agreements**”) with Shanghai Institute of Materia Medica, CAS, and Topharman Shanghai (the “**LV232 Assignors**”), acquiring exclusive intellectual property rights related to LV232 controlled by the LV232 Assignors on a global scale. The salient terms of the LV232 Agreements are summarized below:

- | | |
|---|--|
| Rights Transferred | <ul style="list-style-type: none">• We acquired exclusive rights to research, develop, manufacture, and commercialize LV232 for all potential indications worldwide. |
| Allocation of Responsibilities | <ul style="list-style-type: none">• In general, the LV232 Assignors are obligated to transfer the related patent application documents to us and assist with the ownership transfer procedures upon receipt of relevant payment. The LV232 Assignors are also obligated to provide technical support for the preclinical study and clinical development of LV232. Any fees incurred as a result of providing such technical support will be borne by us.• We are obligated to advance the research, development, manufacturing, and commercialization of LV232. |
| Payments | <ul style="list-style-type: none">• We agreed to pay an assignment fee in installments to the LV232 Assignors, along with a low single-digit royalty based on the annual sales revenue of LV232. |
| Intellectual Property Arrangements | <ul style="list-style-type: none">• For inventions made by us obtained through conducting follow-up researches, we retain sole ownership of the intellectual property rights. However, the LV232 Assignors will be named as co-applicants for inventions related to the crystal form and salt compound of LV232, and forfeit any other rights under applicable laws and regulations.• For inventions made by the LV232 Assignors obtained through conducting follow-up researches, they retain sole ownership of the intellectual property rights. The potential assignment of these rights will be negotiated in a separate agreement. |

BUSINESS

Term and Termination

- The terms of the LV232 Agreements are 20 years, unless there is an earlier termination mutually agreed upon by the parties.
- According to the LV232 Agreements, royalty payment obligations will terminate upon the later of (i) 10 years since the launch date of a product under this project in every country or region, and (ii) when the legal protection term of a patent that protects the product expires in the respective country or region.
- We have the right to terminate the LV232 Agreements in the event of (1) force majeure, (2) the discontinuation of the clinical studies due to technical difficulties that cannot be overcome, and (3) material defects in the technology that cannot be cured within two years by the LV232 Assignors. Additionally, we have the right to voluntarily terminate the LV232 Agreements.
- If the LV232 Agreements are terminated, the rights assigned by the LV232 Assignors shall revert to them. In such a case, LV232 Assignors shall negotiate with us regarding the rights we are entitled to due to the research efforts we have undertaken.

According to CIC, the terms of the LV232 Agreements are in line with industry norms.

TPN171 Agreements

Starting in 2017, we entered into a series of agreements, including a technology development and a supplemental agreement (the “**TPN171 Agreements**”) with Shanghai Institute of Materia Medica, CAS, Topharman Shanghai, and Shandong Topharman (the “**TPN171 Assignors**”), acquiring exclusive intellectual property rights related to TPN171 controlled by the TPN171 Assignors on a global scale. Topharman Shanghai and Shandong Topharman are controlled by our founder Dr. Shen, who is a researcher, group leader, and doctoral supervisor at Shanghai Institute of Materia Medica, CAS.

The salient terms of the TPN171 Agreements are summarized below:

Rights Transferred

- We acquired exclusive rights to research, develop, manufacture, and commercialize TPN171 for all potential indications worldwide.

BUSINESS

- Allocation of Responsibilities**
- In general, the TPN171 Assignors are obligated to transfer the related documents including patent applications, know-how, preclinical study results and any clinical data and IND approval to us, and upon receipt of relevant payment, assist with the ownership transfer procedures of patents or patent applications.
 - Topharman Shanghai is obligated to provide technical support, with any fees incurred to be borne by us.
 - We are obligated to advance the research, development, manufacturing, and commercialization of TPN171. Shanghai Institute of Materia Medica, CAS is obligated to assist us in the clinical development of TPN171.
- Joint Steering Committee**
- The role of the Joint Steering Committee is limited to providing guidance, coordination, supervision, and suggestions for our consideration. It does not have the authority to modify or make final decisions.
 - Specifically, the Joint Steering Committee can provide advice on clinical trial design, recommend clinical sites, CROs and statistical institutes, oversee the proper implementation of clinical development plan, and assist in resolving issues arising from the clinical studies.
- Payments**
- We agreed to pay an assignment fee to Topharman Shanghai and Shandong Topharman.
 - For the intellectual property rights controlled by Shanghai Institute of Materia Medica, CAS in China, we agreed to pay an assignment fee in installments to Shanghai Institute of Materia Medica, CAS, along with a low single-digit royalty based on sales revenue of TPN171 in China.
 - For the intellectual property rights controlled by Shanghai Institute of Materia Medica, CAS outside China, we agreed to pay an assignment fee in installments to Shanghai Institute of Materia Medica, CAS, along with a low single-digit royalty based on sales revenue of TPN171 outside China.

BUSINESS

Intellectual Property Arrangements

- For all patent rights transferred under the TPN171 Assignment Agreements, the Shanghai Institute of Materia Medica, CAS reserves the right to be named as co-applicants, but forfeit any other rights under applicable laws and regulations in China, except for the rights to receive payments pursuant to the TPN171 Agreements.
- According to the agreement between Shanghai Institute of Materia Medica, CAS and us, each party retains sole ownership of the rights to apply for patent applications of any new inventions created or developed solely by such party, while the right to apply for patent applications of any inventions created jointly between the TPN171 Assignors and us will be jointly owned.
- According to the agreements between Shandong Topharman, Topharman Shanghai and us, we shall be the sole owner of the intellectual property rights to any new inventions created by any party.

Term and Termination

- The terms of the TPN171 Agreements are 20 years, unless there is an earlier termination mutually agreed upon by the parties.
- The agreement between Shanghai Institute of Materia Medica, CAS and us can be terminated in the event of (1) force majeure, (2) the discontinuation of the clinical studies not attributable to us, or (3) any objective obstacles that lead to the disruption and termination of the studies.
- The agreement between Shandong Topharman and us can be terminated in the event of (1) force majeure, (2) the discontinuation of the clinical studies attributable to us, or (3) actions or liabilities of Shandong Topharman that render the agreement no longer performable.

BUSINESS

- Shanghai Institute of Materia Medica, CAS may terminate its agreement with us in the event of the discontinuation of clinical studies attributable to us. However, unless the clinical development of TPN171 for ED or PAH treatment is completely terminated globally, the agreement between Shanghai Institute of Materia Medica, CAS, and us cannot be terminated due to force majeure or the discontinuation of clinical studies. We have the right to voluntarily terminate our agreement with Shanghai Institute of Materia Medica, CAS. However, the rights assigned by Shanghai Institute of Materia Medica, CAS shall revert to it.

According to CIC, the terms of the TPN171 Agreements are in line with industry norms.

OUR PROPRIETARY TECHNOLOGY PLATFORMS

Leveraging our extensive expertise in pharmacology, including PD, molecular structure design, chemical synthesis process development, clinical research, and translational studies, we have established multiple technology platforms focused on three key R&D areas essential for the discovery and development of small molecule innovative drugs: (1) rapid discovery of innovative therapeutic compounds, (2) investigation and optimization of the discovered compounds, and (3) clinical research and translational medicine for innovative drugs. Our technology platforms encompass all the key drug development functionalities, and enables us to identify and address potential clinical and manufacturing issues early in the development process so we can direct our efforts towards compounds with the best potential to become clinically active, cost-effective and commercially viable drugs. These proprietary platforms enable us to achieve end-to-end R&D capabilities, efficiently translating innovative drugs from bench to bedside.

Drug Discovery Solutions

Innovative Drug Discovery Platform for Antiviral Drugs

Infectious diseases caused by viruses have posed a significant threat to global public health and imposed a substantial burden on the global economy. Since the establishment of the Public Health Emergency of International Concern pursuant to the International Health Regulations in 2005, the WHO has declared multiple virus outbreak-related international public health emergencies and warned of the potential for more severe global pandemics caused by viral infection in the future. To address currently identified viral infection and potential future viral outbreaks promptly, we have developed an innovative drug discovery platform for antiviral drugs, incorporating two key technologies: nucleoside analogs design technology and prodrug design technology.

BUSINESS

Nucleoside Analogs Design Technology Based on Viral Polymerases

Polymerase serves as an important target for broad-spectrum antiviral drugs. This enzyme is responsible for the replication of viral genetic material and features a highly conserved active site. Unlike conventional enzyme inhibitors, nucleoside analogs do not directly inhibit the activity of polymerase. Instead, through the function of polymerase, the phosphorylated nucleosides from nucleoside analogs are incorporated into newly synthesized viral genomes. This results in the termination of the viral DNA or RNA extension or induces lethal mutations, thereby exerting antiviral effects.

Due to the unique antiviral mechanism of action, the structural variability, the unpredictable nature of nucleoside phosphorylation levels, and the complex interactions among the polymerase, substrates, and viral nucleic acid chains, the rational design of antiviral nucleoside analogs presents significant challenges. We have synthesized numerous nucleoside analogs with diverse structures and conducted extensive antiviral activity studies targeting DNA and RNA viruses. Leveraging these research results, we have developed a nucleoside analogs design technology based on viral polymerases. This platform incorporates a range of internally developed methods and strategies aimed at enhancing antiviral activity, minimizing toxicity, optimizing pharmacokinetic properties, and identifying scenarios where phosphorylation modifications are necessary.

The power of this platform has been validated through our development of the Core Product VV116. At the onset of the COVID-19 outbreak, our research found that a compound exhibited superior antiviral activity against COVID-19 in Vero E6 cells compared to remdesivir. Leveraging this platform, we subsequently co-discovered and developed VV116, an effective antiviral drug against COVID-19. As of the Latest Practicable Date, VV116 had been approved for marketing in China and Uzbekistan.

Prodrug Design Technologies for Nucleoside-based Drugs

Many nucleosides including those that are already marketed, exhibit deficiencies in certain properties, such as low oral bioavailability (making them unsuitable for oral administration), and difficult to phosphorylate.

Nucleosides can be converted into various prodrug forms, including fatty acid esters, amino acid esters, carbamates, phosphodiesteres, phosphoramidates, and base prodrugs, each with unique pharmacokinetic characteristics. The choice of prodrug form depends on the intrinsic properties of the nucleoside molecule and the intended therapeutic indication.

Leveraging prodrug design technologies, we have established a comprehensive and robust prodrug technology library for nucleoside-based drugs. Using this library, we co-discovered the Core Product VV116, a tri-isobutyryl prodrug with optimal oral PK. Currently, we are also developing VV261, a prodrug we co-discovered leveraging this technology for SFTSV treatment.

BUSINESS

Innovative Drug Discovery Platform for Neuropsychiatric Disorders

Neuropsychiatric disorders are widely recognized as one of the disease areas with a lack of effective treatments supported by validated clinical outcomes, resulting in significant medical needs. However, due to complex pathogenic mechanisms and challenges such as the difficulty of penetrating the BBB, the development success rate of innovative drugs in this field remains low.

To address these challenges, we have independently developed an innovative drug discovery platform for neuropsychiatric disorders. The platform is featured by multi-target strategy-based drug discovery, enhanced compound BBB permeability, and a diversified *in vivo* evaluation system for drugs targeting neuropsychiatric disorders, among other core technologies.

Multi-target Strategy-based Drug Discovery

The pathogenesis of neuropsychiatric disorders is complex. Therefore, for neuropsychiatric disorders, targeting a single pathway may not cure the diseases. Based on our insights of the pathogenesis of these diseases, we have identified appropriate target combinations and developed a multi-target strategy for innovative drug discovery. Compounds discovered based on this technology can simultaneously target multiple pathological processes of the disease, producing a synergistic therapeutic effect and potentially achieving comprehensive symptom improvement for such diseases. Additionally, the multi-target combination can reduce specific drug-related side effects by balancing the effects on different targets.

Using this technology, we have co-discovered several drug candidates, including LV232, and VV119. This allows drug candidates to target multiple pathways, exerting a synergistic effect to effectively control the diseases. LV232 is designed for the treatment of depression. It regulates the 5-HTT and 5-HT₃ to achieve a therapeutic effect for depression treatment while reducing common gastrointestinal side effects, thus improving patient compliance. Compared to positive control, an antidepressant that selectively blocks serotonin reuptake, LV232 demonstrated improved therapeutic effects in both mouse and rat models of depression and was undergoing a Phase II clinical trial in China as of the Latest Practicable Date. VV119 has a unique multi-target activity profile, regulating both serotonin and dopamine receptors. It aims to treat both positive and negative symptoms of schizophrenia, as well as improve cognition. According to our preclinical *in vivo* studies, VV119 can exert therapeutic effects for schizophrenia in animal models. As of the Latest Practicable Date, it was in the Phase I clinical stage.

BUSINESS

Structural Modification Techniques to Improve Blood-brain Barrier Permeability

BBB plays a critical role in maintaining the homeostasis of the brain's microenvironment but also blocks almost all of small molecule drugs from crossing into the brain. This presents a significant challenge for the development of innovative drugs for neuropsychiatric disorders that require BBB penetration.

Leveraging years of experience in medicinal chemistry, we have developed structural modification techniques to improve compound permeability across the BBB. By modifying compound structures, we increase lipophilicity and rigidity, reduce hydrogen bond donors, and decrease the acid dissociation constant and total polar surface area, thereby enhancing the BBB penetration rate of compounds. Using this technology, we co-discovered our Core Product LV232, a compound with high BBB penetration rate.

Diversified in Vivo Evaluation System for Drugs Targeting Neuropsychiatric Disorders

The complex pathogenesis of neuropsychiatric disorders presents significant challenges for new drug development in this field. Disease animal models based on different causes and comprehensive behavioral evaluations are key to improving the success rate of drug development in this area. Leveraging extensive experience in neuropsychiatric drug research, we have successfully established a diversified *in vivo* evaluation system for new drugs targeting neuropsychiatric disorders, laying a solid foundation for efficient drug development in this field.

This system comprises internally developed animal models of diseases and animal behavioral evaluation methods. The disease models include depression models, schizophrenia models, Alzheimer's disease models, and Parkinson's syndrome models, each based on different etiologies. Behavioral evaluation methods cover various aspects such as motor function, cognitive function, emotional states, social functions, pain levels, and sexual function. Utilizing this evaluation system, we can systematically assess the efficacy of candidate compounds, such as antidepressant, anxiolytic, and cognitive-enhancing effects, and comprehensively evaluate potential side effects during the preclinical stage, including addiction, motor function abnormalities, sexual dysfunction, sleep disorders, nausea, and vomiting.

We have utilized this *in vivo* evaluation system as an integral part of our drug development process. For example, we have employed this system to evaluate the efficacy of the antidepressant candidate LV232 and the antipsychotic candidate VV119.

BUSINESS

Innovative Drug Discovery Platform for Reproductive Health Diseases

Reproductive health is a critical area of pharmaceutical development due to its profound influence on both individual well-being and overall societal health. To address this, we have established an innovative drug discovery platform for reproductive health diseases, featuring “structural fine-tuning” technology driven by pharmacokinetic properties and animal model construction technology for sexual dysfunction.

- *Pharmacokinetics-guided “structural fine-tuning” technology.* Drugs aimed at improving sexual quality of life have specific pharmacokinetic requirements, such as the need for rapid absorption to reach effective concentrations after administration. Therefore, the development of these drugs requires balancing compound activity with pharmacokinetic properties. We have applied structural modification and synthetic strategies to develop a pharmacokinetics-guided “structural fine-tuning” technology. Based on this technology, we have co-discovered VV913, a candidate for the treatment of PE. Preclinical studies indicated that compared to the positive control, VV913 showed significant efficacy at a lower dose and with fewer side effects.
- *Sexual dysfunction animal model construction technology.* The pathogenic factors underlying sexual dysfunction are complex and multifaceted, making the systematic development of animal models that accurately simulate the characteristics of these conditions particularly challenging in drug discovery. To address this, we have independently developed a range of animal models to comprehensively evaluate the pharmacological efficacy of candidate compounds.

The most common sexual dysfunctions in men are PE and ED. For PE, we have constructed various classic animal models, including the chemical compound-induced rat model for PE, the chemical compound-induced ejaculation rat model, and a natural PE rat model obtained through large-scale animal screening. These models are used to assess therapeutic effect of a compound and its overall influence on sexual behavior. Using these models, we have evaluated the efficacy of the candidate compound VV913 for treating PE.

For ED, we have developed various animal models, including Type I and Type II diabetic-associated ED rat models and nerve injury-related ED models.

In women, HSDD is the most common form of sexual dysfunction. For HSDD, we have developed a libido reduction model in ovariectomized female rats receiving estradiol injections.

BUSINESS

CMC Solutions

“Control From Root Design” Oriented Green Synthesis Process R&D Platform

Leveraging our extensive experience in the synthesis of API, we put forward the concept of “control from root design” firstly and develop APIs’ green manufacturing technology, which primarily focuses on synthetic route design with a comprehensive consideration of regulatory requirements, chemical and process factors, and environmental impact. By adopting this green manufacturing technology, our synthesis processes and conditions reinforce our competitive edge within the industry and support green, sustainable development.

Based on this platform, we have successfully developed synthetic processes for the APIs of various drug candidates and marketed drugs, such as our Core Products LV232 and VV116. During the development of the API synthetic process of our Core Product LV232, we developed a highly efficient synthetic route involving a three-component cyclization reaction followed by an amide reduction reaction. This strategy significantly reduced production costs, avoided environmental risks of heavy metal contamination, and ensured product quality. During the development of the synthetic process for the VV116 API, we developed a “protecting group-free esterification and later deuteration” synthesis process. This innovation reduced the production cycle by half, reduced the generation of pollutants, greatly lowered overall costs, and successfully achieved the one-time production of 500 kilograms of API in a single batch.

Formulation Development Platforms

Based on the clinical needs of specific indications, as well as the molecular structure and physicochemical properties of drug candidates, we utilize our proprietary formulation development platforms to design the most suitable formulation and optimize its manufacturing process. These platforms encompass a wide range of formulation types, including oral solid dosage forms (e.g., tablets, capsules), injectables, and topical formulations.

Clinical Needs-oriented Formulation Development Platform

Our clinical needs-oriented formulation development platform effectively addresses solubility challenges, enabling the creation of stable, highly bioavailable, safe, and effective drug candidates. Core products VV116, LV232 and TPN171, as well as VV119 have been optimized through advanced solubilization techniques, excipient selection, and other formulation development strategies. For example:

- During the formulation development of VV116, we harnessed this technology and implemented various solubilization strategies to enhance its oral bioavailability, ensuring safe and effective administration. These efforts culminated in the issuance of two formulation process patents (patent application numbers: 202111521657.9 and 202211033295.3).

BUSINESS

- For LV232, we applied this technology to identify the most suitable excipients and optimize formulation processes, resulting in a simple, controllable prescription process and stable formulation products. This work led to the granting of a formulation process patent (patent application number: 202410069923.6).
- In the case of VV119, we employed the most effective solubilization methods and incorporated targeted excipients to enhance product stability. This approach improved the *in vitro* dissolution rate, delivering a formulation with consistent quality and high bioavailability, thereby ensuring both efficacy and clinical safety.
- For TPN171, we utilized this technology to address the high activity and solubility characteristics of the API. By optimizing the formulation process, we achieved a simple, cost-effective, and environmentally friendly prescription process suitable for industrial-scale production. This innovation significantly reduced the drug’s production costs, establishing a strong foundation for future commercial cost control. The corresponding research has been granted into a formulation process patent (patent application number: 202210079753.0).

Formulation Development Platform for Improved New Drugs

While meeting the demand for conventional dosage forms of innovative drugs, we have also focused on market needs and unmet clinical demands by developing improved innovative formulation technologies. Based on this technology, we developed an oral mucosal delivery dosage form for our Core Product TPN171. Compared to traditional oral tablets, this dosage form enables faster drug absorption and a shorter onset time, offering a potentially better treatment option for patients with ED. The related research has been granted into formulation process patents (patent application numbers: 202310453339.6, 202410492769.3, and 202410492777.8).

Clinical Development Strategy and Planning

We have established a translational medicine and clinical development platform, supported by a skilled clinical management team and a clinical development team with extensive experience and expertise, ensuring the seamless progression of clinical research and optimal drug efficacy.

Drug Clinical Research Strategies Based on Quantitative Pharmacology

We apply MIDD techniques supported by quantitative pharmacological models to guide clinical trial design, and integrate this technology throughout the entire clinical development process. This approach shortens development timeline and reduces R&D costs.

BUSINESS

In the development of VV116 dry suspension for the treatment of RSV, we constructed population PK and physiologically-based PK models for adults based on the drug’s physicochemical properties, non-clinical research data, and PK data of adults. These models, combined with physiological differences between infants and adults, were used to extrapolate the initial pediatric dosing. By studying the relationships between efficacy evaluation indicators, virological markers, safety indicators, and drug exposure levels, a rational dosing regimen for Phase II clinical trials was recommended.

During the development of TPN171, physiologically-based PK models were used to evaluate drug-drug interactions between TPN171 and mild or moderate inducers of CYP3A4, enabling the waiver of clinical trials and providing a basis for dose adjustments in combination therapies. In the first-in-human study of VV261, PK-PD models were employed to estimate the maximum recommended starting dose and the effective dose for humans, which facilitated the formulation of a rational dose-escalation plan for Phase I clinical trials.

Clinical Development Guided by Positron Emission Tomography

Given the complexity of the pathophysiological characteristics of depression, no widely accepted or recommended objective biomarkers currently exist for assessing depressive symptoms, posing a challenge for the clinical development of such drugs.

In the Phase I clinical trial of LV232, our clinical team utilized positron emission tomography technology to visually and quantitatively assess the drug’s target occupancy in specific regions of the brain. This provided scientific evidence for determining dosing regimens in Phase II clinical trials.

RESEARCH AND DEVELOPMENT

We consistently devote resources to research and development to pave for long-term growth. We believe the diversification and expansion of our product pipeline through both in-house research and development and external collaborations are critical to our long-term competitiveness and success. In 2023 and the nine months ended September 30, 2024, the amount of research and development expenses attributed to our Core Products was RMB50.3 million and RMB42.4 million, respectively, accounting for 38.3% and 42.2% of our total research and development expenses in the respective period. Our R&D centers, located in Suzhou and Shanghai with an aggregate GFA of over 8,000 sq.m., are equipped with advanced laboratories and state-of-art equipment and instruments.

R&D Team

As of September 30, 2024, we have established a dedicated in-house R&D team of 148 members with an average of more than 10 years of industry experience and more than 50% of our R&D team members held master’s or above degrees. The functions of our R&D team span the entire spectrum of hit discovery, lead optimization, druggability evaluation and PCC identification, preclinical research, CMC development, clinical study and regulatory affairs. All the key R&D team members involved in the development of our Core Products have been with us throughout the Track Record Period and up to the Latest Practicable Date.

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Our R&D team is led by Dr. Tian, our founder, chairman of the Board, executive Director, chief executive officer and general manager of our Company, having accumulated over 20 years of robust experience in the pharmaceutical industry. Dr. Tian has been appointed as an industrial professor by Suzhou University and was awarded as a “Key Industry Urgently-needed Talent (重點產業緊缺人才)” by Suzhou government authorities. In addition, Dr. Tian led or participated in a number of national scientific research projects, such as Major Science and Technology Special Project for “Significant New Drugs Development” (“重大新藥創制”科技重大專項) and the National High-tech R&D Program (“863 Program”). Dr. Tian obtained his doctor’s degree in medicinal chemistry from Shanghai Institute of Materia Medica, CAS.

In addition to Dr. Tian, core members of our R&D team also include Dr. HU Tianwen, Dr. WANG Zhiqiang and Dr. YANG Rulei. Dr. Hu, our deputy general manager mainly responsible for the management and R&D strategy of our Group, has more than 10 years of experience in R&D of innovative drugs. As a prolific author, Dr. Hu has published more than 20 Science Citation Index (SCI) research papers. In addition, Dr. Hu has participated in a number of provincial science and technology projects as project leaders or core members. Dr. Hu obtained his doctor’ degree in organic chemistry from the Xinjiang Technical Institute of Physics and Chemistry Technology of the CAS. Dr. Wang, our deputy general manager mainly responsible for the supervision and execution of clinical trials, has more than 20 years of experience in R&D of innovative drugs. Dr. Wang has led the clinical development and regulatory submissions for more than 10 innovative drugs. Dr. Wang obtained his doctor’ degree in pharmacology from China Pharmaceutical University (中國藥科大學). Dr. Yang, head of our manufacturing team, has more than 10 years of industry experience. Before joining us, Dr. Yang worked in prominent pharmaceutical companies such as Suzhou Kelun Pharmaceutical Research Co., Ltd. (蘇州科倫藥物研究有限公司), Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (正大天晴藥業集團股份有限公司) and Suzhou Suncadia Biopharmaceutical Co., Ltd. (蘇州盛迪亞生物醫藥有限公司) (a wholly-owned subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江蘇恒瑞醫藥股份有限公司)). Dr. Yang obtained his doctor’s degree in Chinese medicines from Nanjing University of Chinese Medicine (南京中醫藥大學).

Research and Development Process

Before commencing a research and development project, we perform thorough market analysis to determine whether the drug candidate has unmet medical needs, is commercially viable, is expected to be able to achieve widespread acceptance in the marketplace, and for a generic drug candidate, whether the market for the drug will have high barriers to entry and the drug will be the first generic version on the market. We carefully select research and development projects by balancing the unmet medical needs and commercial potential (including potential competition and market size) of the drug and its likelihood of successful development.

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Our pharmaceutical product development process typically involves the following milestone stages and the actual timing of each stage could vary significantly depending on the subject and nature of the project and the resources committed to the project:

Development stage	Description
Pre-clinical	<ul style="list-style-type: none">• Discovery of lead molecules through evaluation under screening platform, biological assays and PK assays• Optimization of lead molecules and identification of clinical trial samples via pharmacology studies, PK studies and safety assessments• Development of formulation strategies and manufacturing processes• Characterization of clinical trial samples, identification of critical quality attributes and performance of stability studies• Manufacturing of clinical trial samples
IND application	<ul style="list-style-type: none">• Application for pre-IND communication• Submission of IND application
Phase I clinical trials	<ul style="list-style-type: none">• Human PK and drug tolerance evaluation trials
Phase II clinical trials	<ul style="list-style-type: none">• Preliminary exploration on the therapeutic efficacy• Dosage finding for phase III clinical trials
Phase III clinical trials	<ul style="list-style-type: none">• Confirmation of the therapeutic efficacy and safety
NDA	<ul style="list-style-type: none">• Application for approval of new drug registration from the NMPA• Review of the application materials, on-site inspections and final assessments by the NMPA
Launch	<ul style="list-style-type: none">• Marketing approval from the NMPA for new drug registration is obtained; new drug certificate and drug approval number are granted• Mass production commences

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Collaboration with Third Parties

In addition to conducting our core R&D activities in-house, we also engage reputable CROs to manage, conduct, and support our and clinical trials. We select CROs based on various factors, such as professional qualifications, research experience in the related fields, service quality and efficiency, industry reputation, and pricing. Depending on the type of services needed, we enter into service agreements with our CROs on a project-by-project basis, which set out detailed work scope, procedures, timeline and payment schedule. We closely supervise our CROs to ensure they perform in a manner that complies with our protocols and applicable laws, which in turn protects the integrity and authenticity of the data from our trials and studies.

Below is a summary of the key terms of an agreement we typically enter into with our CROs:

- **Services.** The CROs provide us with services in the course of our and clinical trials, such as clinical project management, clinical supervision and report preparation.
- **Term.** The CROs are required to perform their services within the prescribed time limit set out in each work order, usually on a project basis.
- **Payments.** We are required to make payments to the CROs in accordance with a payment schedule agreed by the parties.
- **Intellectual property rights.** We own all intellectual property rights arising from the projects conducted by the CROs within the stipulated work scope.
- **Confidentiality.** Our CROs are not allowed to disclose confidential information, including but not limited to, any technical materials, research reports or trial data related to the project specified in the agreement, and such obligation may survive the termination of the agreement.

For risks relating to CROs, see “Risk Factors — Risks Relating to Our Reliance on Third Parties — We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.”

In addition to working with CROs, we collaborate with Independent Third Parties to better leverage internal and external resources and accelerate the drug discovery process. The terms of these collaboration agreements are tailored on a project-by-project basis and typically define the specific research activities each party will undertake. Our responsibilities may include compound design and synthesis, evaluation of pharmacogenetic properties, *in vitro* activity testing, animal model studies, mechanism of action studies, *in vivo* pharmacokinetic research, and/or preliminary safety evaluations, at our own expense. Intellectual property

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rights resulting from these collaborations are typically co-owned by both parties, with the proportion of rights determined based on each party’s respective contributions to the project. These agreements may be terminated by mutual consent or due to force majeure events that render performance partially or entirely impossible. In the event of an uncured breach by one party, the compliant party retains the right to claim full ownership of all intellectual property related to the project that has been generated or will be generated in the future pursuant to the agreements.

MANUFACTURING

Manufacturing Facility

As of the Latest Practicable Date, we have one manufacturing facility (“**Lianyungang Facility**”) located in Lianyungang, Jiangsu Province, with an aggregate GFA of approximately 51,955 sq.m., housing one workshop for small molecule drugs in oral solid dosage forms and one workshop for APIs. Our Lianyungang Facility has obtained GMP certificate.

Our Lianyungang Facility is fully equipped with advanced automated equipment such as wet graining line (濕法制粒連線), plastic bottle/aluminum plastic packaging line (塑瓶/鋁塑包裝連線), automatic tablet press machine (自動壓片機), automatic capsule filling machine (自動膠囊充填機), reactor (反應釜), drying box (乾燥箱) and centrifuge (離心機). Our production equipment is generally aged from 10 to 15 years. We carry out maintenance and repair work in compliance with applicable regulatory requirements and we replace or upgrade our production equipment when necessary to enhance productivity. We believe our production facilities and equipment are in good working condition.

Lianyungang Facility commenced operations in June 2024 with an annual designed manufacturing capacity of 100 million capsules and 600 million tablets. The following table sets forth the designed production capacity, actual production volume and utilization rates of the small molecule drug production lines of Lianyungang Facility in the three months ended September 30, 2024:

Production lines	Designed production capacity	Production Volume	Utilization rate⁽¹⁾
	<i>(10,000 pills)</i>	<i>(10,000 pills)</i>	<i>(%)</i>
Tablets	15,000	28.1	0.2
Capsules	2,500	27.1	1.1

Note:

- (1) Utilization rate is calculated by dividing the production volume by the designed production capacity. The utilization rate of our product lines is relatively low since our products are at the early stage of commercialization. We expect such utilization rate will increase gradually as our currently commercialized products further develop the relevant market and more products enter the commercialization stage in future.

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Expansion Plan

Considering the favorable support from local government, we are in the process of establishing a new manufacturing facility in Qingdao (“**Qingdao Facility**”) in accordance with international GMP standards. With a GFA of approximately 11,272 sq.m., this new manufacturing facility is expected to support our efforts in exploring formulation and indication expansion opportunities. With such manufacturing facility, we will be able to establish a dual north-south manufacturing network, further enhancing our manufacturing efficiency and improving the accessibility of our drugs. Qingdao Facility is expected to complete construction by the end of 2026.

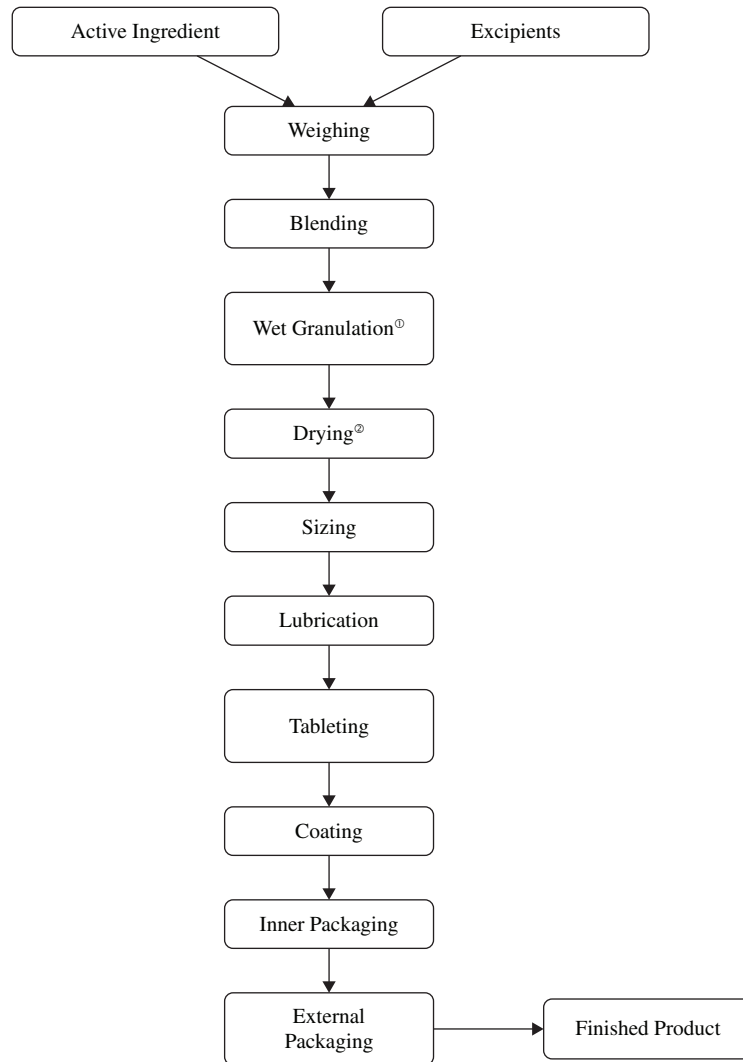
Manufacturing Process

Our manufacturing processes vary between each dosage form and product and the production time varies depending on the specific requirements of the product and manufacturing process.

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Manufacturing Process for Tablets

The following diagram summarizes the manufacturing process for TPN171, VV116, dapoxetine hydrochloride, rebamipide and brexpiprazole tablets, which takes approximately five days.



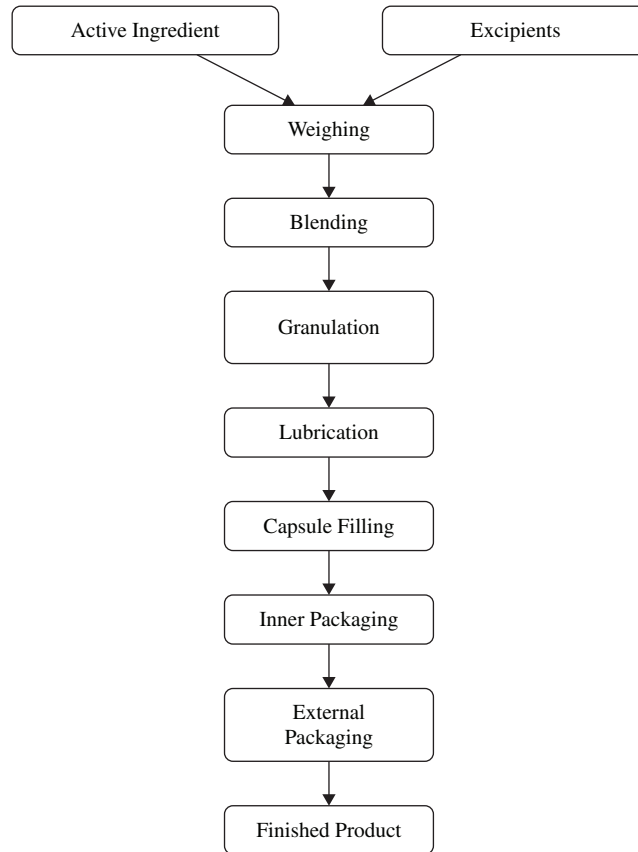
Notes:

- (1) Not required for dapoxetine hydrochloride tablets;
- (2) Not required for dapoxetine hydrochloride tablets.

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Manufacturing Process for Capsules

The following diagram summarizes the manufacturing process for LV232, which takes approximately five days.



Collaboration with Third Parties

During the Track Record and Period and up to the Latest Practicable Date, we had worked with qualified CMOs to manufacture our drug candidates and drugs mainly under following circumstances: (i) before Lianyungang Facility commenced operations; (ii) to manufacture certain drug candidates requiring manufacturing conditions that are not yet available in Lianyungang Facility. We select CMOs by taking into account a number of factors, such as their manufacturing capacity, qualifications, relevant expertise, reputation, track record, product quality and applicable regulations and guidelines. We have adopted, and will continue to implement, procedures to ensure that the production qualifications, facilities and processes of our CMOs comply with the applicable regulatory requirements and our internal guidelines and quality standards. For more information, please see “— Quality Control.”

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Key terms of the agreements that we typically enter into with our CMOs are set forth below.

- **Services.** The CMOs provide us with manufacturing services according to quality standards and prescribed time frame as set out in the agreement.
- **Quality control.** CMOs are obliged to ensure that the quality of products meet the quality standards set out in the agreement and requirements of GMP and other regulations.
- **Payments.** We are required to make payments to the CMOs in accordance with the payment schedule set forth in the agreement, which is typically linked to the stages of the manufacturing process and the deliverables we receive.
- **Intellectual property rights.** We own all intellectual property rights arising from the outsourced manufacturing processes.
- **Confidentiality.** Our CMOs are not allowed to disclose confidential information, including but not limited to, any technical materials, research reports or trial data related to the project specified in the agreement, and such obligation may survive the termination of the agreement.
- **Remedies for non-conforming products.** If the CMOs fail to deliver products or comply with substantial obligations under the relevant agreement, we are entitled to terminate the agreement and request for liquidated damages.

For risks relating to CMOs, see “Risk Factors — Risks Relating to Our Reliance on Third Parties — We rely on third parties to satisfy a portion of our manufacturing needs and our business could be harmed if those third parties fail to provide us with sufficient quantities of the drug products or fail to do so at acceptable quality levels or prices.”

Inventory Management

Our inventory primarily consists of finished products, work in progress and raw materials. We have established an inventory management system that monitors each stage of the warehousing process. Our warehousing personnel are responsible for the inspection, storage and distribution of raw materials and finished products. All raw materials and products are stored in different areas in our warehouses according to their respective storage condition requirement, properties, usage and batch number. Our warehousing personnel regularly check to ensure consistency among the raw material or product, warehouse card and logbook.

We closely monitor our inventory levels and generally keep six-month stock of our finished products. We generally purchase raw materials based on their useful lives and required lead time.

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QUALITY CONTROL

We believe that an effective quality control system is critical to ensure the quality of our products and maintaining our reputation and success. We have been granted ISO9001 certification for our quality management system. Our senior management team is actively involved in formulating internal quality control policies and monitoring our overall quality control process. We have established comprehensive quality control procedures and protocols that span across the entire production lifecycle from raw material sourcing till the final products are delivered to customers. Our quality control personnel are independent from our manufacturing team and are responsible for the implementation of such procedures and protocols. Most of our quality control personnel have pharmaceutical or related educational background. We also conduct regular training so that our quality control personnel understand the regulatory requirements applicable to the operation of our production facility. In addition, we utilize equipment and devices to inspect, test and ensure the quality of our raw materials, production-in-progress and final products.

Key aspects of our quality control procedures are as follows:

Raw Material Quality Control

We purchase raw materials used in our production only from qualified suppliers. Please see “— Raw Materials and Suppliers” for more details about our supplier selection procedures.

We examine our incoming raw materials to confirm they meet our quality requirements. Our warehousing personnel verify the incoming raw materials by various measures before taking delivery, such as inspect the appearance for intactness, checking label information and requesting supplier’s certificate of analysis. When the incoming raw materials are not in compliance with the acceptance criteria, warehousing personnel are required to report to our QA team, and our QA team will decide the solution according to the specific situation.

Production In-process Quality Control

Our advanced automated production equipment is able to screen out and discard semi-finished products that fail to meet quality standards during the production process. In addition, our QC team conducts sample testing on certain semi-finished products at particular stages of production to ensure that they meet our quality standards, such as physical appearance, ingredient composition and drug content.

Our QA team is responsible for verifying that our production processes continuously comply with GMP requirements. We require our production operators to adhere to our standard operating and equipment operation procedures and our QA team regularly inspects our production processes on-site.

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Final Product Quality Control

Each batch of final products is subject to a sample tests. Before we deliver our final products to customers, our QA team inspects the documentation relating to the quality of a product, including its batch records, laboratory testing records, production process records and other information that may impact product quality. Our QA team verifies that final products comply with GMP and other applicable regulations and makes the final decision as to whether the products can be released for sale.

MARKETING AND SALES

During the Track Record Period, we sold dapoxetine to pharmacy chains in China directly or indirectly through distributors, as well as VV116 to corporate and individual customers in Uzbekistan.

In-house Sales and Marketing Team

Our in-house sales and marketing team is primarily responsible for the promotion of our products through various marketing activities and sales through different channels in China and Uzbekistan. As of September 30, 2024, our in-house sales and marketing team included 11 employees, with an average of approximately 13 years of pharmaceutical industry-related experience, and approximately 50% of them held bachelor’s degrees or above in medicine, pharmacy or related majors. We believe that an in-house sales and marketing team with a relatively high level of industry knowledge and expertise is important to implement our academic marketing approach and to maintain our reputation and brand image. We regularly provide in-house trainings to our sales and marketing personnel to enhance their knowledge about our products and professional skills.

Our sales and marketing personnel are required to strictly adhere to our detailed procedures, policies and guidelines, including but not limited to a code of conduct on interacting with, and promoting our products to, healthcare professionals. Please see “— Risk Management and Internal Control.”

Marketing

Marketing Activities

We place strong emphasis on the academic marketing and promotion of our products. We organize and participate in a wide variety of academic conferences, seminars and symposia, on which we communicate with these healthcare professionals about the usage, efficacy, safety and latest clinical research results of our products. In addition, our commercialization team visits healthcare professionals at our target hospitals and other medical institutions regularly to provide them with the most updated product information. These academic marketing activities not only enable us to obtain the requests and feedback of our products from healthcare professionals timely, but also promote our brand and product awareness among healthcare professionals.

BUSINESS

Sales

Direct Sales

We sell dapoxetine directly to pharmacy chains in China. We enter into standardized annual direct sales agreements with these pharmacy chains while individual sales orders are separately entered into for each purchase. Pursuant to such annual direct sales agreements, our direct sales customers are generally required to sell such product in designated geographic area. Our selling prices to direct sales customers are typically fixed during the term of the direct sales agreements. Direct sales customers pay to us on a monthly basis based on actual sales for that month. We are responsible for the delivery of our products to our direct sales customers at our own costs. We have been selling dapoxetine to direct sales customers in China since May, 2024. As of September 30, 2024, we engaged 14 direct sales customers in China. For the nine months ended September 30, 2024, the revenue attributable to our direct sales customers was RMB0.2 million, accounting for 41.1% of the revenue generated from sales of dapoxetine in China.

Distributors

We also sell dapoxetine to distributors, which distribute such product to pharmacy chains in China. We benefit from our distributors’ established distribution channels and local resources to save costs, and to increase the effectiveness of launching and selling our products in our target markets within a short period of time. We have been selling dapoxetine to distributors in China since May, 2024. As of September 30, 2024, we engaged five distributors in China. To the best knowledge of our Directors, during the Track Record Period, all of our distributors were Independent Third Parties. For the nine months ended September 30, 2024, the revenue attributable to our distributors was RMB0.3 million, accounting for 58.9% of the revenue generated from sales of dapoxetine in China.

We enter into distribution agreements with our distributors. Individual sales contracts or purchase orders are generally separately entered into or placed for each purchase. Key terms of our distribution agreements include:

- ***Term.*** Typically one year.
- ***Designated distribution area.*** Distributors are generally not allowed to sell or distribute our products outside of their designated distribution areas.
- ***Payment.*** Our selling prices to distributors are typically fixed during the term of the distribution agreements.
- ***Resale price management.*** We generally do not control the prices at which our distributors resell our products to their customers.

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- ***Inventory level.*** We generally do not require our distributors to maintain a minimum inventory level.
- ***Return of products.*** We generally do not allow product returns except for defective products.
- ***Sub-distributors.*** We do not have contractual relationships with sub-distributors engaged by our distributors, nor do we manage such sub-distributors directly. Instead, we rely on our distributors to supervise their respective sub-distributors.
- ***Access to information.*** Distributors are required to provide us with information including but not limited to sales and inventory data of our product.
- ***Confidentiality.*** Both parties have non-disclosure obligations, and undertake to only use each other's trade secrets and other business information only for the purpose of relevant agreement and not to disclose such trade secrets or other business information to any third party.
- ***Termination.*** We may terminate the distribution agreements in the event of, among others, any material breach by our distributors, such as sales outside of their designated distribution areas.

Selection and Management of Distributors

We select our distributors based on their proven distribution capabilities, knowledge of their target markets, warehouse management, financial stability, credit records and expertise and experience of their management teams. We require all our distributors to possess all licenses and permits necessary for the sales and distribution of pharmaceutical products.

During the Track Record Period, we did not terminate our business relationship with any distributors due to their breach of their distribution agreements or their non-compliance with regulatory requirements.

In order to manage the risk of cannibalization of sales among our distributors, we specify the designated geographic area for which our distributors are responsible in our distribution agreements with them. The agreements also prohibit distributors from distributing our products outside their respective designated geographic areas. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any material cannibalization or competition among our distributors within the same geographical area. Our Directors are of the view that the above measures are sufficient to mitigate potential cannibalization and competition among distributors.

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We have implemented the following policies and measures to mitigate the risk of inventory accumulation in the distribution channels. Distributors are required to provide us with information including but not limited to sales and inventory data of our product. We maintain a database of distributors' inventory, which is able to monitor distributors' inventory levels and alert automatically when inventory exceeds the set level. We also review and evaluate sales data of our distributors on a regular basis, which enables us to make periodic assessments of actual market demand for our products. We actively adjust our sales strategy and geographic or product coverage of each distributor based on market demand and each distributor's capacity. During the Track Record Period and up to the Latest Practicable Date, we did not notice any abnormally high inventory level of our distributors.

Logistics Arrangement

We engage a third-party logistics service provider to transport our products to our direct sales customers and distributors in China. We have entered into logistics service agreement with such provider, pursuant to which they are responsible for any loss caused by their negligence during the course of their logistics services, including transfer, loading, unloading, transportation and delivery to our customers.

PRODUCT RETURNS AND WARRANTIES

We generally do not accept any product returns, except for defective products. We may also consider returning products by taking into account the specific scenario and our business relationships with our direct sales customers and distributors. For defective products, we are fully responsible for the cost of return and replacement of these products. We provide warranties on our qualifications and products. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material compliant or product returns due to quality problems.

PRICING

In PRC, for our products commercialized or to be commercialized in near future, we implement different pricing strategies depending on whether the product is included in the NRDL. For the products which are included or planned to include in the NRDL, such as rebamipide, our pricing will align with the medical insurance reimbursement standards and be subject to dynamic adjustment mechanism. For the products that we do not have plan to include in the NRDL in the near future, such as TPN171 and dapoxetine, we determine their prices based on a number of factors, including our costs of production, prices of competing drugs, our technology advantages, differences in features between our drugs and competing drugs, affordability of patients and changes in the levels of supply and demand.

In Uzbekistan, our pricing may not exceed a specified allowable markup on the ex-factory price in accordance with relevant regulations. Within the above price range, our products are priced based on a number of factors, including prices of competing drugs, our technology advantages, differences in features between our drugs and competing drugs, affordability of patients and changes in the levels of supply and demand.

BUSINESS

INTELLECTUAL PROPERTY

Our continued success depends on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates, our core technologies and other know-how. We also have internal protocols in place to ensure that we operate without infringing, misappropriating or otherwise violating the proprietary rights of others, and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. We protect our proprietary and intellectual property by, among other methods, filing patent applications related to our proprietary technology, inventions and improvements. We also rely on trade secrets and know-how to develop and maintain our proprietary and intellectual property, which we generally seek to protect through contractual obligations with third parties.

As of the Latest Practicable Date, we had 22 registered trademarks, three trademark applications and three domain names, which we consider to be material to our business. As of the Latest Practicable Date, we held 81 issued patents including 39 issued patents in China and 42 issued patents in other jurisdictions, and 78 patent applications including 35 patent applications in China, 36 patent applications in other jurisdictions, and seven patent applications under PCT. As of the Latest Practicable Date, for our Core Products, we held 31 issued patents including eight issued patents in China and 23 issued patents in other jurisdictions, and 30 patent applications including six patent applications in China and 24 patent applications in other jurisdictions. The following table summarizes the details of our granted patents in connection with our Core Products:

Product	Patent Name	Patent Type	Patentee	Jurisdiction	Patent Status	Patent Expiration ⁽¹⁾
VV116	Antiviral use of nucleoside analogs or combinations containing nucleoside analogs	Invention	Our Company, Shanghai Institute of Materia Medica, CAS, the Wuhan Institute of Virology, CAS, and Xinjiang Technical Institute of Physics and Chemistry, CAS ⁽²⁾	Macau, U.S., India, Australia, Japan and China	Granted	2041-04-16
VV116	Preparation of a nucleoside analog VV116	Invention	Our Company, Vigonvita Lianyungang, Shanghai Institute of Materia Medica, CAS, and the Wuhan Institute of Virology, CAS ⁽²⁾	China	Granted	2042-01-26

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Product	Patent Name	Patent Type	Patentee	Jurisdiction	Patent Status	Patent Expiration ⁽¹⁾
VV116	A nucleoside analog salt and its crystal form, pharmaceutical composition and uses	Invention	Our Company, Shanghai Institute of Materia Medica, CAS, and the Wuhan Institute of Virology, CAS ⁽²⁾	China	Granted	2041-10-21
LV232	A paracyclic compound, its preparation and its use	Invention	Our Company and Nantong Hefeng	China and Japan	Granted	2040-05-29
TPN171	Compound containing pyrimidinone phenyl group, pharmaceutical composition thereof, preparation method and use thereof	Invention	Our Company and Shanghai Institute of Materia Medica, CAS ⁽²⁾	Canada, U.S., Japan, Germany, Australia, China, France, U.K., Korea, Russia and Mexico	Granted	2029-12-10
TPN171	Salts of phenylpyrimidone compounds, polymorphs of crystals and their pharmaceutical compositions and uses	Invention	Our Company and Shanghai Institute of Materia Medica, CAS ⁽²⁾	Germany, EPO, Japan, China, Russia, U.S., Australia and Korea	Granted	2038-07-02
TPN171	Pharmaceutical composition containing phenylpyrimidinone hydrochloride, pharmaceutical preparation containing the same, and preparation and use thereof	Invention	Our Company and Vigonvita Lianyungang	China	Granted	2042-01-24

Notes:

- (1) Patent expiration does not include any applicable patent term extensions.
- (2) Pursuant to the relevant assignment agreements, the assignors reserve the right to be named as co-applicants, but forfeit any other rights under applicable laws and regulations in China, except for the low single-digit royalty based on the annual sales revenue of VV116 on a global scale. See “— Collaboration Arrangement.”

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The following table summarizes the details of our patent applications in connection with our Core Products:

Product	Patent Name	Patent Type	Applicant	Jurisdiction	Patent Status
VV116	Antiviral use of nucleoside analogs or combinations containing nucleoside analogs	Invention	Our Company, Shanghai Institute of Materia Medica, CAS, the Wuhan Institute of Virology, CAS, and Xinjiang Technical Institute of Physics and Chemistry, CAS ⁽¹⁾	China, South Africa, Canada, New Zealand, Brazil, Israel, Indonesia, Singapore, Colombia, Hong Kong, Mexico, U.S., EPO, Uzbekistan, EAPO, Korea, Philippines, Saudi Arabia and Thailand	Pending
VV116	Preparation of an antiviral nucleoside analog	Invention	Our Company, Shanghai Institute of Materia Medica, CAS, and the Wuhan Institute of Virology, CAS ⁽¹⁾	China	Pending
VV116	A nucleoside analog salt and its crystal form, pharmaceutical composition and uses	Invention	Our Company, Shanghai Institute of Materia Medica, CAS, and the Wuhan Institute of Virology, CAS ⁽¹⁾	U.S., Japan and EPO	Pending
VV116	Pharmaceutical composition for oral deuterated nucleoside or pharmaceutically acceptable salt thereof, preparation method and application	Invention	Our Company, Shanghai Institute of Materia Medica, CAS, the Wuhan Institute of Virology, CAS, and Vigonvita Lianyungang ⁽¹⁾	China	Pending
LV232	Pharmaceutical composition containing paracyclic compound, preparation method and use	Invention	Our Company and Vigonvita Lianyungang	China	Pending
LV232	Salt of an antidepressant compound, method for preparing the same, pharmaceutical composition containing the same, and use of the same	Invention	Our Company and Shanghai Institute of Materia Medica, CAS ⁽¹⁾	China	Pending
LV232	A paracyclic compound, its preparation and its use	Invention	Shanghai Institute of Materia Medica, CAS and Nantong Hefeng	EPO and U.S.	Pending

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Product	Patent Name	Patent Type	Applicant	Jurisdiction	Patent Status
TPN171	Compound containing pyrimidinone phenyl group, pharmaceutical composition thereof, preparation method and use thereof	Invention	Our Company and Shanghai Institute of Materia Medica, CAS ⁽¹⁾	Uzbekistan	Pending
TPN171	An orally disintegrating tablet and its preparation	Invention	Our Company and Vigonvita Lianyungang	China	Pending

Note:

- (1) Pursuant to the relevant assignment agreements, the assignors reserve the right to be named as co-applicants, but forfeit any other rights under applicable laws and regulations in China, except for the low single-digit royalty based on the annual sales revenue of VV116 on a global scale. See “— Collaboration Arrangement.”

Our IP Legal Adviser has conducted freedom to operate (FTO) analysis of our Core Products, the result of which indicates that there is no material infringement risk for our Core Products against valid and enforceable patents of any third party issued in China. FTO analysis is a patent investigation, based on a search of patent databases, which is commonly used to determine whether any existing patents cover a company’s product, and whether that product would infringe any existing patents. However, we cannot provide any assurance that all relevant third party patents were identified or that conflicting patents will not be issued in the future. For more information, see “Risk Factors — Risks Relating to Our Intellectual Property Rights.”

For more details of our other intellectual property rights, please see Appendix VII.

The term of an individual patent may vary based on the countries/regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent.

We rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our drug candidates and related technologies. We seek to protect our proprietary technologies and processes, in part, by entering into confidentiality arrangements with third-party contractors. We have contractual arrangements with key employees and employees involved in research and development, pursuant to which intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property. We also have established relevant internal policy governing the confidentiality of our information.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material proceedings in respect of, and we had not received written notice of any material claims of infringement of any intellectual property rights, in which we may be a claimant or a respondent. However, there are risks if we fail to protect our intellectual property rights in the future. For risks relating to our intellectual property, see “Risk Factors — Risks Relating to Our Intellectual Property Rights.”

BUSINESS

CUSTOMERS

Our customers primarily consist of our out-licensing customers, as well as our direct sales customers and distributors which directly purchase pharmaceutical products from us, as well as pharmaceutical companies to which we provide CRO services. During the Track Record Period, we provide CRO services in order to optimize the resource allocation of our experimental facilities and equipment and supplement our cash flow. In 2023 and the nine months ended September 30, 2024, our revenue generated from our five largest customers in each year/period during the Track Record Period in aggregate accounted for 99.3% and 94.2% of our total revenue in the respective year/period, respectively, and revenue generated from our largest customer alone in each year/period during the Track Record Period accounted for 51.1% and 79.9% of our total revenue in each respective year/period, respectively. The following table sets forth details of our five largest customers in each year/period during the Track Record Period:

Five Largest Customers for the Year Ended December 31, 2023	Customers' Background	Products/ Services Provided	Commencement of Business Relationship	Credit Term	Revenue Contribution	Percentage of Total Revenue
					<i>(RMB'000)</i>	<i>(%)</i>
Customer A	Based in Shanghai, China, a company mainly engaged in R&D of biopharmaceuticals and vaccines	Out-licensing	2021	10 days	102,101.8	51.1
Customer B	Based in Hainan Province, China, a company providing APIs and medical equipment	Assignment of contractual commercial rights ⁽¹⁾	2023	5 days	94,339.6	47.3
Customer C	Based in Beijing, China, a company mainly engaged in R&D of pharmaceutical products	CRO services	2020	10 days	648.6	0.3
Customer D	Based in Hebei Province, China, a company mainly engaged in drug R&D and sales	CRO services	2019	10 days	581.4	0.3
Customer E	Based in Henan Province, China, a company mainly engaged in drug R&D and sales	CRO services	2016	10 days	542.5	0.3
Total					198,213.9	99.3

Note:

- (1) We assigned our exclusive rights as the API provider for VV116 for the treatment of COVID-19 globally, except for five countries in Central Asia (i.e., Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (i.e., Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (i.e., Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan) and Russia, to Customer B for eight years pursuant to the VV116 Out-Licensing Agreements.

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Five Largest Customers for the Nine Months Ended September 30, 2024	Customers' Background	Products/Services Provided	Commencement of Business Relationship	Credit Term	Revenue Contribution <i>(RMB'000)</i>	Percentage of Total Revenue <i>(%)</i>
Customer A	Based in Shanghai, China, a company mainly engaged in R&D of biopharmaceuticals and vaccines	Out-licensing and CRO services	2021	10 days	7,982.6	79.9
Customer F	Based in Zhejiang Province, China, a company mainly engaged in drug R&D, manufacturing and sales	CRO services	2024	7 days	796.7	8.0
Customer G	Based in Guangdong Province, China, a company mainly engaged in drug R&D, manufacturing and sales	CRO services	2018	10 days	283.0	2.8
Customer H	Based in Jiangsu Province, China, a company mainly engaged in drug research and sales	CRO services	2018	10 days	216.7	2.2
Customer I	Based in Jiangsu Province, China, a company mainly engaged in drug sales	pharmaceutical products	2024	30 days	140.2	1.4
Total					9,419.1	94.2

To the best of knowledge of our Directors, all of our five largest customers in each year/period during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest customers in each year/period during the Track Record Period.

BUSINESS

RAW MATERIALS AND SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of (i) IP assignors; (ii) suppliers of raw materials and consumables for the R&D of our drug candidates; (iii) suppliers of APIs, excipients and packaging materials for the manufacturing of our drugs; (iv) third party contractors including CROs and CMOs.

Currently, we procure raw materials mainly from suppliers in China. We have established stable collaboration relationships with qualified suppliers for raw materials, which we believe have sufficient capacity to meet our demands. Nevertheless, we believe that adequate alternative sources for such supplies exist. We select our suppliers by considering their qualifications, compliance with relevant regulations and industry standards, manufacturing facilities, production quality, prices, business scale, market share, reputation, and after-service quality. During the Track Record Period, we did not experience any material disputes with suppliers, difficulties in procurement, or interruptions in our operations due to a delay in delivery of raw materials.

See “— Research and Development — Collaboration with Third Parties” for details on our relationships with the CROs and “— Manufacturing — Collaboration with Third Parties” for details on our relationships with the CMOs.

In 2023 and the nine months ended September 30, 2024, our purchases from our five largest suppliers in each year/period during the Track Record Period in aggregate accounted for 36.5% and 44.7% of our total purchases in the respective year/period, respectively, and purchases from our largest supplier alone in each year/period during the Track Record Period accounted for 16.5% and 24.5% of our total purchases in each respective year/period, respectively. The following table sets forth details of our five largest suppliers in each year/period during the Track Record Period:

Five Largest Suppliers for the Year Ended December 31, 2023	Suppliers' Background	Products/Services Supplied	Commencement of Business Relationship	Credit Term	Purchase Amount	Percentage of Total Purchase
					(RMB'000)	(%)
Supplier A	Based in Shanghai, China, an innovative drug research institution	Mainly IP assignment	2016	30 days	18,512.5	16.5
Shandong Topharman Pharmaceutical Co., Ltd. (山東特諾曼藥業有限公司)	Based in Shandong Province, China, a company providing APIs and CMO services	APIs and CMO services	2015	10 days	10,009.8	8.9
Supplier B	Based in Guangdong Province, China, a PRC listed company providing CRO services	CRO services	2021	10 days	4,820.8	4.3

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Five Largest Suppliers for the Year Ended December 31, 2023	Suppliers' Background	Products/Services Supplied	Commencement of Business Relationship	Credit Term	Purchase Amount <i>(RMB'000)</i>	Percentage of Total Purchase <i>(%)</i>
Supplier C	Based in Jiangsu Province, China, a company providing CRO services	CRO services	2019	14 days	4,258.2	3.8
Supplier D	Based in Zhejiang Province, a PRC and HK Listed company providing CRO services	CRO services	2019	15 days	3,393.1	3.0
Total					40,994.3	36.5
Five Largest Suppliers for the Nine Months Ended September 30, 2024	Suppliers' Background	Products/Services Supplied	Commencement of Business Relationship	Credit Term	Purchase Amount <i>(RMB'000)</i>	Percentage of Total Purchase <i>(%)</i>
Supplier B	Based in Guangdong Province, China, a PRC listed company providing CRO services	CRO services	2021	7 days	14,547.0	24.5
Supplier E	A comprehensive hospital based in Shanghai, China	Clinical trial services	2017	10 days	4,061.9	6.8
Supplier A	Based in Shanghai, China, an innovative drug research institution	Mainly IP assignment	2016	20 days	3,807.9	6.4
Supplier C	Based in Jiangsu Province, China, a company providing CRO services	CRO services	2019	14 days	2,071.8	3.5
Supplier F	Based in Jiangsu Province, China, a company providing CRO services	CRO services	2021	5 days	2,058.5	3.5
Total					26,547.0	44.7

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To the best of knowledge of our Directors, except for Shandong Topharman, all of our five largest suppliers in each year/period during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers in each year/period during the Track Record Period, except for Shandong Topharman. In addition, we believe that we have adequate alternative sources for such suppliers, and we have developed alternative sourcing strategies to decrease our reliance on existing suppliers. We will establish necessary relationships with alternative sources based on our assessment on the risk of supply continuity.

COMPETITION

The pharmaceutical industry is evolving and highly competitive. We face competition from other pharmaceutical companies and emerging biotechnology companies engaged in the research, development, production, marketing or sales of pharmaceutical products. Our products primarily compete with products that are indicated for similar conditions as our products on the basis of efficacy, safety, compliance and convenience. For more information on the competitive landscape of our drug candidates, please see “Industry Overview” and “— Innovative Drug Candidates.”

We expect the competition will become more intensive in the future as additional players enter into the segments. The identities of our key competitors vary by product and, in certain cases, our competitors may have greater financial and research and development resources than us, may elect to focus these resources on developing, importing or in-licensing and marketing products in China that are substitutes for our products and may have broader sales and marketing infrastructure with which to do so. For potential impact of market competition, please see “Risk Factors — Risks Relating to Sales and Distribution and Commercialization of our Drugs and Drug Candidates — We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our revenue and profitability and our ability to successfully commercialize our drug candidates.”

We believe our continued success will depend on our following capabilities: the capability to develop innovative products and advanced technologies; the capability to apply technologies to all production lines; the capability to develop an extensive product portfolio; the capability to maintain a highly efficient operational model; the capability to attract, retain and cultivate talent; the capability to maintain high quality standards; the capability to obtain and maintain regulatory approvals; and the capability to effectively market and promote products.

BUSINESS

AWARDS AND RECOGNITION

The table below sets forth the key selected awards and recognitions we have received as of the Latest Practicable Date.

Award/Project	Year	Award/Grant Authority
Specialized and Innovative “Little Giant” Enterprises (專精特新“小巨人”企業)	2024	Ministry of Industry and Information (工信部)
Leading Enterprises in Suzhou Cultivation Program of Enterprises Enhanced by Intellectual Property (蘇州市知識產權強企培育工程引領型企業)	2024	Suzhou Municipal Market Supervision Administration (蘇州市市場監督管理局)
Potential Unicorn Companies in Jiangsu Province (江蘇省潛在獨角獸企業)	2023	Productivity Centre of Jiangsu Province (江蘇省生產力促進中心)
Jiangsu Province Specialized, Refined, Unique and New Small and Medium Enterprises (江蘇省專精特新中小企業)	2023	Jiangsu Provincial Department of Industry and Information Technology (江蘇省工業和信息化廳)
Gazelle Enterprises in Hi-Tech Development Zone of Jiangsu Province (江蘇省高新技術產業開發區瞪羚企業)	2023	Productivity Centre of Jiangsu Province (江蘇省生產力促進中心)
Hi-Tech Enterprise (高新技術企業)	2022	Jiangsu Provincial Science and Technology Department, Jiangsu Provincial Finance Department, and Jiangsu Provincial Tax Bureau of the State Administration of Taxation (江蘇省科技廳、江蘇省財政廳、國家稅務總局江蘇省稅務局)
List of Landmark Enterprises with Biological Pharmaceutical Industry Potential in Suzhou City (蘇州市生物醫藥產業潛力地標企業培育名單)	2022	Suzhou Municipal Bureau of Industry and Information Technology (蘇州市工業和信息化局)

BUSINESS

HEALTH, SAFETY, SOCIAL AND ENVIRONMENTAL MATTERS

We acknowledge our environment protection and social responsibilities and are aware of the environmental, energy, climate-related and workplace safety issues that may impact our Group’s business operation. We are committed to complying with environmental, social and governance (“ESG”) reporting requirements upon the [REDACTED].

We are subject to various environment, health and safety (“EHS”) related laws and regulations in China. To ensure our compliance with applicable environmental protection, health and safety laws and regulations, we (i) have established various guidelines governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials wastes, and taken measures to ensure such guidelines are strictly enforced; (ii) inspect our equipment and workplaces regularly to identify and eliminate safety hazards; and (iii) keep health records for all employees and conduct health examinations during their time at the Company, especially for employees engaged in work involving occupational hazards.

During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant PRC environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or impact on the operations of our business during the period.

Governance of Environmental and Social Matters

Our Board has overall responsibility for (i) overseeing and determining our Group’s environmental, social, and climate-related risks and opportunities that impact our Group, (ii) establishing ESG related targets of our Group, (iii) adopting the ESG related policies, and (iv) reviewing our Group’s performance in ESG matters.

We are subject to environmental-related and social related risks and climate-related issues. See “Risk Factors — Risks Relating to Government Regulations — We are subject to environmental protection, health and safety laws and regulations, and failure to comply with them could result in fines, penalties, or costs that may materially adversely affect the success of our business.” We may adopt more ESG policies relating to social responsibility and internal governance as our Board deems fit. Our Board takes full responsibility to our ESG strategy and reporting. Our Board may assess the ESG risks and review our existing strategy, target and internal controls. Necessary improvements will be implemented to mitigate the risks. At the same time, we are committed to the sustainable growth and long-term development of the company.

BUSINESS

Environmental Matters

Hazardous Waste

We have adopted internal policies for environmental risk prevention to ensure compliance with the requirements of the applicable national, industrial and local standards, laws, regulations and policies. In particular, we (i) store hazardous waste in special warehouse and have contracted with qualified third parties for the disposal of hazardous waste; and (ii) conduct regular inspections of the special warehouse containing hazardous wastes, in order to make sure that respective containers are intact.

We monitor our hazardous waste on a periodic basis and make continuous efforts in working towards the target of reducing the hazardous waste discharge. Our hazardous waste discharge levels amounted to approximately 55.8 tons and 39.3 tons in 2023 and the nine months ended September 30, 2024, respectively. Once we accumulated certain amount of hazardous waste, we transfer such waste to relevant warehouse, which will later be removed and disposed by third-party qualified waste disposal companies. The waste disposal companies would issue written records for the transfer of hazardous wastes and we keep such records for our internal review and compliance. In 2023 and the nine months ended September 30, 2024, we incurred costs in relation to hazardous waste disposal of approximately RMB0.4 million and RMB0.2 million, respectively. We will make continuous endeavors to take measures to protect the ecological environment during our business operation, so as to minimize adverse environmental impact.

Resource Consumption

To reach our goal for sustainable development, we oversee our environmental protection performance in various aspects, such as efficiency in the use of resources and energy consumption. We monitor our electricity consumption levels and implement measures to improve energy efficiency. In 2023 and the nine months ended September 30, 2024, our electricity expenses were approximately RMB2,475.6 thousand and RMB1,556.4 thousand, respectively.

Following the ESG evaluation system standards in China and the market practice of industry pioneers, we aim to avoid or reduce the adverse impact on the environment caused by our operations and services, formulate environmental management plans to continuously improve our energy consumption efficiency and ensure all of our operations comply with governmental environment-related regulations and requirements. Our current target is to establish a comprehensive ESG governance mechanism for our Company and the historical energy consumption levels during the Track Record Period will serve as a foundation for developing more relevant energy reduction strategies and settling appropriate reduction targets for us in the future.

BUSINESS

Climate Change

In view of the nature of our business, to the best knowledge of our Directors, the climate change will not have any major impact on our business operation. In the case of extreme natural weather, we will actively respond to the relevant policies of local government, make contingency plans to ensure the safety of our staff. In the case of acute physical risks such as direct damage to assets and indirect impacts from supply chain disruption as a result of extreme weather events, we will make corresponding contingency and disaster preparedness plans, and we believe that we have the ability to deal with climate crisis. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of climate-related issues.

Social Matters

We have policies on compensation and dismissal, equal opportunities and anti-discrimination. If our employees encounter any unequal discrimination, they should seek immediate assistance from either their department head, human resources department or our management team. We will immediately follow up, investigate, and, if necessary, report to the law enforcement authorities.

We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees. We also organize regular safety training and exercises for our employees to improve their safety awareness.

EMPLOYEES

As of September 30, 2024, we employed 281 employees, 277 of whom were based in China, four of whom were based in Uzbekistan. The following table sets forth a breakdown of our employees by function as of September 30, 2024.

<u>Function</u>	<u>Number of employees</u>	<u>Percentage</u>
Research and development	148	52.7%
Manufacturing	21	7.5%
Quality control and quality assurance	26	9.3%
Business development, sales and marketing	14	5.0%
Others	<u>72</u>	<u>25.6%</u>
Total	<u>281</u>	<u>100.0%</u>

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We believe our ability to attract, hire, and keep quality employees is indispensable for our success. We primarily recruit employees through job websites and recruitment agencies, taking into account factors including work experience, education, and professional competence. We offer competitive remuneration packages based on qualifications and experience. To ensure compliance with PRC labor laws, we enter into standard individual employment agreements with our employees, covering matters such as terms, wages, bonuses, employee benefits and grounds for termination. We also enter into confidentiality and non-competition agreements with our employees.

As required by PRC regulations, we participate in various government statutory employee benefit plans, including social insurances, namely pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing funds. We are required under PRC law to make contributions to employee benefit plans at specified percentages of the salaries, bonuses and certain allowances of our employees, up to a maximum amount specified by the local government regulations from time to time.

We offer employees a variety of professional development opportunities and encourage a performance-driven environment. We focus on creating a culture to encourage retention and engagement. We conduct new staff training regularly to guide new employees and help them adapt to the new working environment. We also provide training and development programs to our employees from time-to-time to achieve talent growth.

As of the Latest Practicable Date, none of our employees are represented by labor unions. We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with occupational health and safety laws or regulations, and had not experienced any strikes, labor disputes or industrial actions which have had a material effect on our business.

PROPERTIES

Owned Properties

As of the Latest Practicable Date, we owned two properties, including (i) one property with a total GFA of approximately 51,955 sq.m. used for our manufacturing facility located in Lianyungang, Jiangsu Province. See “— Manufacturing — Manufacturing Facility”; and (ii) one property with a total GFA of approximately 24,883 sq.m. used for our new R&D center located in Suzhou, Jiangsu Province.

Except for the property interests set forth in the Property Valuation Report set out in Appendix III to this document, no single property interest that forms part of our non-property activities had a carrying amount representing 15% or more of our total assets as of September 30, 2024.

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Leased Properties

As of the Latest Practicable Date, we leased seven properties with an aggregate GFA of approximately 20,000 sq.m. in China and Uzbekistan, which were primarily used as R&D facilities, manufacturing facilities and offices. The following table sets forth the details of our material leased properties:

<u>No.</u>	<u>Location</u>	<u>Usage</u>	<u>GFA</u>	<u>End of Lease Term</u>
			<i>(Approximate sq.m.)</i>	
1.	Suzhou, Jiangsu	R&D and office	6,187.0	December 31, 2025
2.	Shanghai	R&D and office	2,051.4	July 31, 2028
3.	Qingdao, Shandong	R&D, manufacturing and office	11,271.7	April 30, 2029

As of the Latest Practicable Date, three of our lease agreements in China, with an aggregate GFA of 11,383.9 sq.m., had not been registered with the relevant PRC authorities primarily due to the difficulty of procuring our lessors’ cooperation to register such leases. The registration of such leases will require the cooperation of our lessors. We will continue to liaise with the lessors and try to register all the unregistered leases. As advised by our PRC Legal Adviser, failure to register an executed lease agreement will not affect its legality, validity or enforceability. However, we may be subject to a fine of no less than RMB1,000 and not exceeding RMB10,000 for each unregistered lease agreement if the relevant PRC government authorities require us to rectify and we fail to do so within the prescribed time period. We estimate that the maximum penalty we may be subject to for these unregistered lease agreements will be RMB30,000, which we believe was immaterial.

In the event that any of our leases expire after the end of their respective lease term, we would need to seek alternative premises and incur relocation costs. We believe that there are alternative properties at comparable rental rates available on the market, the use of which would not materially and adversely affect our business operations, and we thus do not rely on the existing leases for our business operations.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. For example, we maintain clinical trial liability insurance, work safety liability insurance and employer’s liability insurance. See “Risk Factors — Risks Relating to our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.” During the Track Record Period, we had not made or been the subject of any material insurance claims.

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LICENSES, PERMITS AND APPROVALS

Our PRC Legal Adviser has advised, that as of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations in China. The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

<u>License/Permit</u>	<u>Issuing Authority</u>	<u>Holder</u>	<u>Grant date</u>	<u>Expiration date</u>
Pharmaceutical Production License (藥品生產許可證)	Jiangsu Medical Products Administration (江蘇省藥品監 督管理局)	Our Company	December 11, 2024	January 9, 2026
Pharmaceutical Production License (藥品生產許可證)	Jiangsu Medical Products Administration (江蘇省藥品監 督管理局)	Vigonvita Lianyungang	September 10, 2024	February 25, 2028

We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable.

LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

As advised by our PRC Legal Adviser, during the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material claims, disputes, litigations, arbitrations, or other legal proceedings. During the same period, we were not involved in any non-compliance incidents which would, individually or in the aggregate, have a material adverse effect on our business as a whole.

We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. For risks and uncertainties relating thereto, see “Risk Factors — Risks Relating to Government Regulations.”

BUSINESS

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations and we recognize that risk management is critical to our success. For a discussion of various operational risks and uncertainties we face, see "Risk Factors." As such, we are committed to establishing, maintaining risk management and internal control systems that are appropriate for us, and we continuously strive to improve these systems. We have prepared written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix C1 to the Listing Rules.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk measures:

- Our Board will be responsible for (i) formulating our risk management policy; (ii) reviewing and approving major risk management issues of our Company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Company; (v) reviewing the relevant departments' reporting on key risks and providing feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our Company; and (viii) reporting to our Audit Committee on our material risks.
- Our Audit Committee will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Company.

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- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Company and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. Our internal control policies set out a framework to identify, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation. Our special inspection personnel will monitor the implementation of our internal control policies, reports the weakness identified to our management and Audit Committee and follows up on the rectification actions.
- Our Directors (who are responsible for monitoring the corporate governance of our Company) with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an Audit Committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Company.
- We have engaged Somerley Capital Limited as our compliance advisor to provide advice to our Directors and senior management team regarding matters relating to the Listing Rules. Our compliance advisor is expected to, upon our consultation, provide advice and guidance in respect of compliance with the applicable laws and Listing Rules including various requirements of directors' duties and internal control in a timely fashion.

BUSINESS

- We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.
- Regarding anti-bribery and anti-kickback, we issued anti-bribery and anti-fraud policy which included compliance training for our personnel, particularly our sales and marketing personnel, and setting whistle-blowing system for non-compliance behavior and penalties for bribery and fraud cases.
- We have established procedures to protect the confidentiality of patients' personal data. We maintain policies which require our personnel to be trained on collecting and safeguarding personal information. We also require our CROs to safeguard the data in their possession. Access to clinical trial data has been strictly limited to authorized personnel only according to the good clinical practice and relevant regulations. Additionally, we require external parties and internal employees involved in clinical trials to comply with applicable confidentiality requirements. Data can only be used for the intended purpose, as agreed by the patients and the data usage shall be consistent with the informed consent form. We have a number of ongoing or planned clinical studies. Any transfer of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable data and privacy protection laws.
- Our Directors believe that compliance creates value for us and dedicate to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behavior across the organization, we regularly conduct internal compliance checks and inspections, adopt strict accountability internally and conduct compliance training.

During the Track Record Period, we had regularly reviewed and enhanced our risk management system and internal control system. We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Dr. Shen, a founder of our Company, was able to exercise approximately 54.97% voting rights in our Company through directly holding 82,461,110 Shares. Ms. Jin Jie, Dr. Shen’s spouse, was able to exercise approximately 1.52% voting rights in our Company through directly holding 2,272,478 Shares.

Immediately upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Dr. Shen and Ms. Jin Jie will be entitled to exercise approximately [REDACTED] voting rights in our Company in aggregate. Therefore, Dr. Shen and Ms. Jin Jie will be regarded as the Controlling Shareholders of our Company under the Listing Rules.

As of the Latest Practicable Date, save for the interest in our Group, our Controlling Shareholders did not have any interest in a business which competes or is likely to compete, directly or indirectly, with the business of our Group, and which requires disclosure under Rule 8.10 of the Listing Rules.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

Our Directors consider that we are capable of carrying on our business independently of our Controlling Shareholders and their close associates after the [REDACTED], taking into consideration the factors below.

Management Independence

Our Board comprises six Directors, including two executive Directors, one non-executive Director and three independent non-executive Directors. We believe that our Board as a whole, together with our senior management, is able to perform the managerial role in our Group independently from our Controlling Shareholders for the following considerations:

- (a) none of our executive Directors or senior management members hold any role as an executive director or member of senior management in any close associates of our Controlling Shareholders;
- (b) each of our Directors is aware of his/her fiduciary duties as a Director which require, among others, that he/she acts for the benefit of and in the best interests of our Company and does not allow any conflict between his/her duties as a Director and his/her personal interests;
- (c) our daily management and operation decisions are made by all our executive Directors and senior management, all of whom have substantial experience in the industry in which we are engaged and will be able to make business decisions that are in the best interest of our Group. For details of the industry experience of our senior management, see “Directors, Supervisors and Senior Management” in this document;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (d) we have appointed three independent non-executive Directors with a view to bringing independent judgment to the decision-making process of our Board;
- (e) in the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and a Director and/or his/her associate, he/she shall abstain from voting and shall not be counted towards the quorum for the voting; and
- (f) we have adopted a series of corporate governance measures to manage conflicts of interest, if any, between our Group and our Controlling Shareholders, which would support our independent management. For further details, see “— Corporate Governance Measures” in this section.

Operational Independence

We have full rights to make all decisions on, and to carry out, our own business operations independently. We have our own departments specializing in the respective areas which have been in operation and are expected to continue to operate independently from our Controlling Shareholders and their close associates. We hold the licenses, intellectual property rights and qualifications necessary to carry on our principal business. We also have independent access to suppliers and customers, and have sufficient capital, facilities and employees to operate our business independently from our Controlling Shareholders and their close associates.

Based on the above, our Directors believe that we will be able to operate independently from our Controlling Shareholders and their close associates.

Financial Independence

We have an independent financial system. We make financial decisions according to our own business needs, and neither our Controlling Shareholders nor their close associates intervene with our use of funds. We have established an independent finance department with a team of finance staff and an independent audit, accounting and financial management system.

In addition, we have been and are capable of obtaining financing from third parties without relying on any guarantee or security provided by our Controlling Shareholders or their close associates. Save as the amounts due to Topharman Shanghai disclosed in the section headed “Financial Information — Related Party Transactions — Outstanding Balances With Related Parties”, which will be settled prior to the [REDACTED], as of the Latest Practicable Date, there was no loan, advance or guarantee provided by our Controlling Shareholders or their close associates.

Based on the above, our Directors believe that we are capable of carrying on our business independently of, and do not place undue reliance on, our Controlling Shareholders and their close associates after the [REDACTED].

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

CORPORATE GOVERNANCE MEASURES

Our Directors recognize the importance of good corporate governance in protecting our Shareholders’ interests. We have adopted the following measures to safeguard good corporate governance standards and to avoid potential conflicts of interests between our Group and our Controlling Shareholders:

- (a) under the Articles of Association, where a Shareholders’ meeting is to be held for considering proposed transactions in which our Controlling Shareholders or any of their respective associates has a material interest, our Controlling Shareholders and their associates will not vote on the relevant resolutions and shall not be counted in the quorum for the voting;
- (b) our Company has established internal control mechanisms to identify connected transactions. Upon [REDACTED], if our Company enters into connected transactions with our Controlling Shareholders or any of their associates, our Company will comply with the applicable Listing Rules;
- (c) our Board consists of a balanced composition of executive Directors and non-executive Directors (including independent non-executive Directors), with independent non-executive Directors representing not less than one-third of our Board to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors individually and collectively possess the requisite knowledge and experience to perform their duties. They will review whether there is any conflict of interests between our Group and our Controlling Shareholders and provide impartial and professional advice to protect the interests of our minority Shareholders;
- (d) where our Directors reasonably request the advice of independent professionals, such as financial advisers, the appointment of such independent professionals will be made at our Company’s expenses; and
- (e) we have appointed Somerley Capital Limited as our compliance adviser to provide advice and guidance to us in respect of compliance with the applicable laws in Hong Kong and the Listing Rules, including various requirements relating to corporate governance.

Based on the above, our Directors believe that sufficient corporate governance measures have been put in place to manage conflicts of interests that may arise between our Group and our Controlling Shareholders and to protect our Shareholders’ interests as a whole after the [REDACTED].

CONNECTED TRANSACTIONS

OVERVIEW

We have entered into certain agreements with parties who will become connected persons of our Company upon [REDACTED] and the transactions contemplated under such agreements will constitute continuing connected transactions of our Company under Chapter 14A of the Listing Rules upon [REDACTED]. Details of such continuing connected transactions of our Company following the [REDACTED] are set out below.

As our Company is eligible for [REDACTED] on the Stock Exchange under Chapter 18A of the Listing Rules as a biotech company, the revenue ratio under Rule 14.07 of the Listing Rules would not be an appropriate measure of the size of relevant continuing connected transactions set out in this section. As an alternative, we have applied a percentage ratio test based on the total expenses of our Group.

RELEVANT CONNECTED PERSONS

Upon the [REDACTED], the following entities with whom we have entered into transactions will be regarded as our connected persons under the Listing Rules:

<u>Connected Person</u>	<u>Connected Relationship</u>
Shandong Topharman	An associate of Dr. Shen, our Controlling Shareholder
Topharman Shanghai	An associate of Dr. Shen, our Controlling Shareholder

ONE-OFF CONNECTED TRANSACTIONS

A. Subject Transfer under the TPN171 Agreements

Background

As disclosed in the section headed “Business” in this document, we have submitted the NDA to the NMPA for the marketing approval of TPN171 for the treatment of ED in China. We anticipate receiving approval from the NMPA around mid 2025.

Principal Terms

Starting in 2017, we entered into a series of agreements (the “**TPN171 Agreements**”) with Shanghai Institute of Materia Medica, CAS, Topharman Shanghai, and Shandong Topharman (“**TPN171 Assignors**”), acquiring exclusive intellectual property rights related to TPN171 controlled by the TPN171 Assignors on a global scale (the “**TPN171 Subject Transfer**”).

CONNECTED TRANSACTIONS

In consideration, we agreed to pay the TPN171 Assignors certain assignment fees, including a total of RMB9.0 million as assignment fee to Topharman Shanghai and Shandong Topharman. As of the Latest Practicable Date, we had paid RMB1.0 million. The remaining payment of RMB8.0 million will be paid after TPN171 receives marketing approval in the PRC. For the details of the salient terms of TPN171 Agreements, please refer to the section headed “Business — Collaboration Arrangement — TPN171 Agreements” in this document.

Listing Rules Implications

As the TPN171 Agreements were entered into prior to the [REDACTED] and the transaction relating to the TPN 171 Subject Transfer is one-off in nature, the transaction (in relation to the outstanding payments to Topharman Shanghai and Shandong Topharman in respect of the consideration for TPN171 Subject Transfer pursuant to the TPN171 Agreements) contemplated thereunder will not be classified as continuing connected transactions under Chapter 14A of the Listing Rules upon the [REDACTED]. Accordingly, the transaction will not be subject to any of the reporting, announcement, annual review and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules. In the event that there are any material changes to the terms and conditions of the TPN171 Agreements, we shall comply with Chapter 14A of the Listing Rules in respect of such agreement as and when appropriate, including, where required, seeking independent shareholders’ approval prior to effectuating such changes.

B. Subject Transfer under the LV232 Agreements

Background

As disclosed in the section headed “Business” in this document, in September 2023, we received the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of LV232 for the treatment of depression. Based on data collected from the completed Phase I clinical trials, we proceeded with a Phase II clinical trial of LV232 for the treatment of depression. We received the approval from the ethics committee for conducting this trial in December 2024, and published the relevant information of the Phase II trial through the official website of the CDE in January 2025.

Principal Terms

On April 16, 2021 and October 23, 2023, Nantong Hefeng entered into an agreement and a supplemental agreement (the “**LV232 Agreements**”) with Shanghai Institute of Materia Medica, CAS, and Topharman Shanghai (the “**LV232 Assignors**”), acquiring exclusive intellectual property rights related to LV232 controlled by the LV232 Assignors on a global scale (the “**LV232 Subject Transfer**”).

CONNECTED TRANSACTIONS

In respect of the LV232 Subject Transfer, Nantong Hefeng agreed to pay a total of for RMB15 million as assignment fee in installments to Topharman Shanghai, of which RMB2.0 million has been paid as of the Latest Practicable Date. For the details of the salient terms of LV232 Agreements, please refer to the section headed “Business — Collaboration Arrangement — LV232 Agreements” in this document.

Listing Rules Implications

As the LV232 Agreements were entered into prior to the [REDACTED] and the transaction relating to the LV232 Subject Transfer is one-off in nature, the transaction (in relation to the outstanding payments in respect of the consideration for LV232 Subject Transfer pursuant to the LV232 Agreements) contemplated thereunder will not be classified as continuing connected transactions under Chapter 14A of the Listing Rules upon the [REDACTED]. Accordingly, the transaction will not be subject to any of the reporting, announcement, annual review and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules. In the event that there are any material changes to the terms and conditions of the LV232 Agreements, we shall comply with Chapter 14A of the Listing Rules in respect of such agreement as and when appropriate, including, where required, seeking independent shareholders’ approval prior to effectuating such changes.

For the Listing Rules implications on the Revenue Sharing (as defined below) pursuant to the LV232 Agreements, see “— Fully-exempt Continuing Connected Transaction — Revenue Sharing under the LV232 Agreements — Listing Rules Implications” in this section.

FULLY-EXEMPT CONTINUING CONNECTED TRANSACTION

Revenue Sharing under the LV232 Agreements

As part of the arrangements under the LV232 Agreements, we agreed to pay the LV232 Assignors with a low single-digit royalty based on the annual sales revenue of LV232 (the “**Revenue Sharing**”). The payment receivable by LV232 Assignors from the us for Revenue Sharing pursuant to the LV232 Agreements will be determined in accordance with the following formula (“**Formula**”):

$$\text{Payment to LV232 Assignors under the Revenue Sharing}^{(1)} = \frac{\text{Net sales revenue}^{(2)} \text{ of LV232} *}{\text{agreed percentage under LV232 Agreements}}$$

Notes:

- (1) The amount of profit receivable by LV232 Assignors will be equally divided between the LV232 Assignors.
- (2) Net sales revenue shall exclude value-added taxes and sales related taxes.

CONNECTED TRANSACTIONS

The Revenue Sharing arrangement will terminate upon the later of (i) 10 years since product launch in a particular country or region, and (ii) when the patent term expires in that country or region.

Reasons for the Transaction

LV232 is a potential first-in-class dual-target 5-HTT/5-HT₃ receptor modulator. With a unique mechanism of action, the two targets of LV232 work synergistically, enhancing the antidepressant effects while reducing gastrointestinal side effects.

LV232 was initially discovered by the LV232 Assignors. Our founder, Dr. Tian, has made significant contributions to the discovery of LV232. After acquiring the global exclusive rights from the LV232 Assignors while LV232 was still in the early preclinical development stage, we determined and evaluated the preclinical candidate and we sponsored and completed preclinical studies and two Phase I clinical trials of LV232. For detailed information regarding the assignment agreements between the LV232 Assignors and us, see “Business — Collaboration Arrangement — LV232 Agreements” in this document. We plan to initiate a Phase II clinical trial of LV232 for the treatment of depressive disorder in China in the first quarter of 2025.

Taking into account the clinical trial stage of LV232, the Revenue Sharing is fair and reasonable and in the interest of our Group and the Shareholders as a whole because (i) it is a common practice to share future sales revenue and proceeds from transfer of intellectual property rights under comparable drug candidate transfer agreements which in turn lowers the upfront fixed payment payable by the licensee in the Chinese biopharmaceutical market, according to CIC; and (ii) the Revenue Sharing contemplated under the LV232 Agreements, including the Formula as stated above, was determined after arm’s length negotiation between LV232 Assignors and us and in the ordinary and usual course of the business of our Group.

Historical transaction amounts

As LV232 has not yet been approved for commercialization by the relevant authorities in the PRC, there was no historical amount received by LV232 Assignors in relation to the Revenue Sharing during the Track Record Period.

Caps on future transaction amounts

As LV232 is still at early clinical development stage, with a plan to initiate a Phase II clinical trial of LV232 for the treatment of depressive disorder in China in the first quarter of 2025, and to commence a short-term Phase III clinical trial in the second half of 2026, the timeline of commercialization of LV232 is of uncertainty. Therefore, it is impracticable and extremely difficult for us to set monetary annual caps for the Revenue Sharing under the LV232 Agreements.

CONNECTED TRANSACTIONS

Listing Rules Implications

Under Rule 14A.52 of the Listing Rules, the period of an agreement for a continuing connected transaction must be fixed and must not exceed three years, except in cases where the nature of the transaction requires the agreement to be a duration longer than three years. The LV232 Agreements has a term commencing from the date of the agreement and continue to be in force until the tenth anniversary of the initial sale of LV232.

Under Rule 14A.53 of the Listing Rules, a listed issuer is required to set a monetary annual cap for the continuing connected transactions.

As the highest applicable percentage ratio in respect of each of the caps as we currently expect is, on an annual basis, within the de minimis threshold provided under Rule 14A.76 of the Listing Rules, such continuing connected transaction will, upon the [REDACTED], be fully exempt from the reporting, annual review, announcement, circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules.

Waiver Application under Rule 14A.52 and Rule 14A.53 of the Listing Rules

We have applied to the Stock Exchange for a waiver from strict compliance with the requirement under Rule 14A.52 of the Listing Rules such that the LV232 Agreements can be of a term commencing from the date of the agreement and continue to be in force until the tenth anniversary of the initial sale of LV232, and automatically extendable for additional consecutive renewal terms of three years each, for so long as our Shares are [REDACTED] on the Stock Exchange, because: (i) LV232 is not expected to be approved for commercialization in near future; and (ii) such a long-term cooperation is in the interest of our Company and the Shareholders as a whole.

Our Directors are of the view, and the Sole Sponsor concur, that, the LV232 Agreements were entered into on normal commercial terms and a longer duration of the agreement will avoid any unnecessary business interruptions and help ensure the long-term stable business development, and it is normal business practice for agreements of this type to be of such duration.

As confirmed by CIC, the LV232 Agreements, including its term and schedule, and the Revenue Sharing contemplated thereunder, are in line with the industry prevailing practice. As such, we believe that the LV232 Agreements are in the interest of our Company and the Shareholders as a whole.

CONNECTED TRANSACTIONS

We have also applied to the Stock Exchange for a waiver from strict compliance with the requirement under Rule 14A.53 of the Listing Rules so as to allow us to set the annual caps in relation to continuing connected transactions under the LV232 Agreements as the Formula in accordance with the terms as set out in the LV232 Agreements for the following reasons:

- (i) There was no historical amount and sufficient data for us to establish a model to estimate the future sales volume and amount for LV232 as it is a newly developed drug without sufficient market data to analyze the extent of acceptance of this drug by the doctors. It is impractical for us to accurately estimate the revenue to be derived from the sale of LV232 depend on the actual addressable market of the product, which will in turn depend on various factors including but not limited to the acceptance by the medical community and patient access, drug pricing, reimbursement and the number of patients, all of which are beyond the control of our Group. Even if we are able to set up a projection model to for calculation purpose, such a model will only present hypothetical predictions, which is not based on scientific analysis using historical data, and could be inaccurate, unreliable and even misleading.
- (ii) Imposing an arbitrary cap on the potential sales volume of LV232 does not demonstrate commercial reasonableness and would be counter-productive as far as the interests of the Group and LV232 Assignors as well as their respective shareholders are concerned. In the absence of a factually and mathematically reliable model to estimate the annual sales volume of LV232, imposing an arbitrary monetary cap may become an arbitrary ceiling on the transaction amount under LV232 Agreements. As far as the transactions are on normal commercial terms, and the profit margin of the LV232 and the percentage under the Revenue Sharing are commercially reasonable and in line with market standards, the interests of our Group, the LV232 Assignors and their respective shareholders are protected, and there is no reason or benefit for the two groups to impose such fixed cap.
- (iii) Given LV232 is in the research and development stage, the disclosure of the annual caps in monetary terms would in effect provide Shareholders and investors as well as competitors of our Company with an indication of our estimated revenue, and may allow them to extrapolate the likely volume of LV232 to be supplied and even the unit supply price of LV232. Such information is highly sensitive and would therefore put us in disadvantageous position in relation to our business operation and competition with other market players.
- (iv) Instead of setting a fixed annual cap on the Revenue Sharing, if there is any material change to the arrangement under the Revenue Sharing, we will re-comply with the applicable rules under Chapter 14A of the Listing Rules, including seeking independent shareholders' approval where the case may so require, so as to further ensure the interest of the shareholders of both our Group and the LV232 Assignors.

CONNECTED TRANSACTIONS

NON-EXEMPT CONTINUING CONNECTED TRANSACTION

API Purchase Framework Agreement

Background

We purchased API with ancillary services for the products including, VV116 and TPN171 from Shandong Topharman during the Track Record Period. Upon [REDACTED], we expect to continue to purchase API with ancillary services from Shandong Topharman for our products.

Principal Terms

On [●], 2025, our Company entered into a framework agreement with Shandong Topharman relating to the purchase of API with ancillary services (the “**API Purchase Framework Agreement**”) for a term commencing from the date of [REDACTED] and continue until December 31, 2027 (both days inclusive), renewable by mutual agreement of the parties, subject to compliance with the requirements under Chapter 14A of the Listing Rules and all other applicable laws and regulations. Pursuant to the API Purchase Framework Agreement, Shandong Topharman agree to supply API with ancillary services to our Group.

Reasons for the Transaction

Shandong Topharman is principally engaged in the research and development, production and sales of API for domestic and overseas demands, with professional teams of research and development, production and management teams, and equipped with advanced and specialized research and development, production and quality control equipment and functions.

We purchased API with ancillary services for our products including VV116 and TPN171, from Shandong Topharman during the Track Record Period. Upon [REDACTED], we expect to continue to purchase API with ancillary services from Shandong Topharman for our products.

In particular, as disclosed in the section headed “Business” in this document, we filed an NDA for TPN171 for the treatment of ED in China in September 2023, and we anticipate to obtain NDA approval around mid-2025. As our only manufacturing facility located in Lianyungang did not commence operations until June 2024, when we filed the NDA for TPN171 for the treatment of ED in China in September 2023, we were not able to manufacture API for TPN171 by ourselves. Considering that Shandong Topharman has established a manufacturing facility and possesses the necessary manufacturing capabilities in respect of API for TPN171, we chose Shandong Topharman, as a competent candidate to provide the API with ancillary services for TPN171 upon the approval of TPN171’s NDA, and indicated that Shandong Topharman would be responsible for the manufacturing upon the approval of TPN171’s NDA when we filed the NDA with CDE. Since the NDA of TPN171 is under the review by CDE, any change of the manufacturer for the anticipated commercialization of TPN171 would result in an additional application with CDE which would affect the process for approval of NDA.

CONNECTED TRANSACTIONS

Taking into account (i) Shandong Topharman's experience and reputation in the industry; (ii) Shandong Topharman's track record in supplying the products to us, particularly their reliability in delivery of our orders in a timely manner and stability of their product quality; (iii) their adequacy in production capacity for meeting our potential demand for API upon commercialization of our products, and (iv) Shandong Topharman's in depth understanding of our product requirements, our Directors believe that they can provide the required products that suit our needs most appropriately and that it will be in the best interests of our Company and our Shareholders to enter into the API Purchase Framework Agreement.

Historical Amounts

The aggregate historical transaction amounts for procurement of API by us from Shandong Topharman for the year ended December 31, 2023 and the nine months ended September 30, 2024 was RMB10,009,835 and RMB1,106,746, respectively.

Annual Caps and Pricing Policy

The estimated maximum amount payable by us to Shandong Topharman for each of the three years ending December 31, 2025, 2026 and 2027 in relation to their supply of API and ancillary services will be RMB3.5 million, RMB4.0 million and RMB6.0 million, respectively.

The proposed annual caps for the three years ending December 31, 2027, being the estimated total amounts payable by our Group as set out above, are determined with reference to:

- (a) the historical prices of API with ancillary services purchased from Shandong Topharman with reasonable discounts to the prices payable to Shandong Topharman based on purchase amount;
- (b) our estimation on the demand for API for the research and development of our products, including TPN171 and VV116 before commercialization;
- (c) our estimation on the market demand for TPN171 and VV116 with reference to our estimated commercialization progress and sales volume;
- (d) our plan to gradually engage our Lianyungang Facility in manufacturing of API for our products.

The proposed annual cap for each of the three years ending December 31, 2027 is significantly less than the historical transaction amounts for the year ending December 31, 2023 as there was one-off bulk purchases for clinical trials of certain products, including TPN171 and VV116 in 2023, while no such bulk purchases is expected to be made for each of the three years ending December 31, 2027 in light of our R&D plan.

CONNECTED TRANSACTIONS

There is an increase trend in the proposed annual caps for the three years ending December 31, 2027 in accordance with the estimation of the demand for API, taking into account (i) our plan to complete the ongoing Phase II clinical trails of VV116 in the second quarter of 2025 and initiate the Phase III clinical study of VV116 in the third quarter of 2025, and (ii) the commercialization plan of VV116 and TPN171.

The fees payable to Shangdong Topharman under the API Purchase Framework Agreement is charged at rates no less favourable than rates at which our Company pays Independent Third Parties for comparable transactions and were determined by our Company and Shangdong Topharman through arm's length negotiation based on a number of factors, including (i) the rates charged by Shangdong Topharman to Independent Third Parties, (ii) the nature, complexity and volume of products we expect to procure from Shangdong Topharman, (iii) the market rates by obtaining and comparing against fee quotes provided by other comparable service providers; and (iv) the estimated cost for the manufacturing of API.

Listing Rules Implications

As the highest applicable percentage ratio of the transactions contemplated under the API Purchase Framework Agreement, for each of the years ending December 31, 2025, 2026 and 2027 calculated for the purpose of Chapter 14A of the Listing Rule is expected to be more than 0.1% but less than 5% on annual basis. Accordingly, such transactions will, upon [REDACTED], constitute continuing connected transactions of our Company subject to the reporting, announcement and annual review requirements but will be exempt from the circular and the independent Shareholders' approval requirement under Chapter 14A of the Listing Rules.

Waiver Application under Rule 14A.105 of the Listing Rules

By virtue of Rule 14A.76(2) of the Listing Rules, the transactions contemplated under the API Purchase Framework Agreement will constitute connected transactions subject to reporting, annual review and announcement requirements under Chapter 14A of the Listing Rules.

As the above non-exempt continuing connected transactions are expected to continue on a recurring, continuing basis and will extend over a period of time, our Directors consider that compliance with the above announcement requirement would be impractical, unduly burdensome and would impose unnecessary administrative costs on our Company. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver to us under Rule 14A.105 of the Listing Rules from strict compliance with the announcement, circular and independent shareholders' approval requirements in respect of the above non-exempt continuing connected transactions.

CONNECTED TRANSACTIONS

DIRECTORS’ CONFIRMATION

Our Directors (including our independent non-executive Directors) consider that (i) the non-exempt continuing connected transactions contemplated under the API Purchase Framework Agreement have been entered into and are conducted in the ordinary and usual course of our business on normal commercial terms or better, and are fair and reasonable and in the interests of our Company and our Shareholders as a whole; and (ii) the proposed annual caps for such continuing connected transactions are fair and reasonable and in the interest of our Company and our Shareholders as a whole.

If any of the terms of the API Purchase Framework Agreement is altered, or if the Company enters into any new agreements with any connected persons (within the meaning of the Listing Rules) in the future, the Company must fully comply with the relevant requirements under Chapter 14A of the Listing Rules unless it applies for and obtains a separate waiver from the Stock Exchange.

SOLE SPONSOR’S CONFIRMATION

Having taken into account (i) the documentation and information provided by our Company; and (ii) due diligence conducted and discussions with our Company and the Industry Consultant, the Sole Sponsor is of the view that (i) the non-exempt continuing connected transactions contemplated under the API Purchase Framework Agreement have been entered into and are conducted in the ordinary and usual course of our business on normal commercial terms or better, and are fair and reasonable and in the interests of our Company and our Shareholders as a whole; and (ii) the proposed annual caps for such continuing connected transactions are fair and reasonable and in the interest of our Company and our Shareholders as a whole.

SHARE CAPITAL

This section presents certain information regarding our share capital prior to and upon the completion of the [REDACTED].

BEFORE THE [REDACTED]

As of the Latest Practicable Date, the registered share capital of our Company was RMB150,000,000, comprising 150,000,000 Unlisted Shares with a nominal value of RMB1.00 each.

UPON THE COMPLETION OF THE [REDACTED]

Immediately upon completion of the [REDACTED], assuming [REDACTED] are not exercised, the share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the total issued share capital
		(%)
Unlisted Shares in issue	100,920,667	[REDACTED]
H Shares to be converted from Unlisted Shares	49,079,333	[REDACTED]
H Shares to be [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	100.00

Immediately upon completion of the [REDACTED], assuming the [REDACTED] is fully exercised, the share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the total issued share capital
		(%)
Unlisted Shares in issue	100,920,667	[REDACTED]
H Shares to be converted from Unlisted Shares	49,079,333	[REDACTED]
H Shares to be [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	100.00

RANKING

Upon completion of the [REDACTED] and conversion of 49,079,333 Unlisted Shares into H Shares, our Shares will consist of Unlisted Shares and H Shares. Both Unlisted Shares and H Shares are ordinary shares in the share capital of our Company. Apart from certain qualified domestic institutional investors in the PRC, certain qualified PRC investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect, and other persons who are entitled to hold our H Shares pursuant to relevant PRC laws and regulations or upon approvals of any competent authorities, H Shares generally cannot be subscribed by or traded among legal and natural persons of the PRC.

SHARE CAPITAL

Unlisted Shares and H Shares are regarded as one class of shares under our Articles of Association, and Unlisted Shares and H Shares will rank pari passu with each other in all other respects and, in particular, will rank equally for all dividends or distributions declared, paid or made after the date of this document. All dividends in respect of our Shares are to be declared and paid by us in Hong Kong dollars or Renminbi. Other than cash, dividends could also be paid in the form of shares or a combination of cash and shares.

CONVERSION OF OUR UNLISTED SHARES INTO H SHARES

All our Unlisted Shares are not [REDACTED] or [REDACTED] on any stock exchange. The holders of our Unlisted Shares may convert their Shares into H Shares provided such conversion shall have gone through any requisite internal approval process and complied with the regulations prescribed by the securities regulatory authorities of the State Council and the regulations, requirements and procedures prescribed by the overseas stock exchange(s) and have been approved by the securities regulatory authorities of the State Council, including the CSRC. The [REDACTED] of such converted Shares on the Hong Kong Stock Exchange will also require the approval of the Hong Kong Stock Exchange.

Based on the procedures for the conversion of our Unlisted Shares into H Shares as disclosed in this section, we can apply for the [REDACTED] of all or any portion of our Unlisted Shares on the Hong Kong Stock Exchange as H Shares in advance of any proposed conversion to ensure that the conversion process can be completed promptly upon notice to the Hong Kong Stock Exchange and delivery of Shares for entry on the H Share register. As any [REDACTED] of additional Shares after our initial [REDACTED] on the Hong Kong Stock Exchange is ordinarily considered by the Hong Kong Stock Exchange to be a purely administrative matter, it will not require such prior application for [REDACTED] at the time of our initial [REDACTED] in Hong Kong.

No class Shareholder voting is required for the [REDACTED] and [REDACTED] of the converted Shares on the Hong Kong Stock Exchange. Any application for [REDACTED] of the converted Shares on the Hong Kong Stock Exchange after our initial [REDACTED] is subject to prior notification by way of announcement to inform Shareholders and the public of such proposed conversion.

After all the requisite approvals have been obtained, the following procedure will need to be completed in order to effect the conversion: the relevant Unlisted Shares will be withdrawn from the Unlisted Share register and we will re-register such Shares on our H Share register maintained in Hong Kong and instruct the [REDACTED] to issue H Share certificates. Registration on our [REDACTED] will be conditional on (a) our [REDACTED] lodging with the Hong Kong Stock Exchange a letter confirming the proper entry of the relevant H Shares on the H Share [REDACTED] of members and the due dispatch of H Share certificates; and (b) the admission of the H Shares to [REDACTED] on the Hong Kong Stock Exchange in compliance with the Listing Rules, [REDACTED] and [REDACTED] in force from time to time. Until the converted shares are re-registered on our [REDACTED], such Shares would not be [REDACTED] as H Shares.

SHARE CAPITAL

RESTRICTION ON TRANSFER OF SHARES ISSUED PRIOR TO [REDACTED]

Pursuant to the PRC Company Law, our Shares issued prior to the [REDACTED] shall not be transferred within one year from the [REDACTED].

REGISTRATION OF SHARES NOT [REDACTED] ON THE OVERSEAS STOCK EXCHANGE

According to the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》), domestic shareholders of unlisted shares shall, in accordance with the relevant business rules of the CSRC, handle the transfer registration of shares, complete the procedures of share registration and stock listing in accordance with the relevant regulations of the Hong Kong market, and disclose information in accordance with the law and regulations. The H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with the CSRC of the shares related to the application has been completed.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and without taking into account any H Shares which may be issued pursuant to the exercise of the [REDACTED], the following persons will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to our Company and the Hong Kong Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company:

Name of Shareholder	Nature of Interest	As of the Latest Practicable Date		Immediately following the [REDACTED] (assuming the [REDACTED] is not exercised)		
		Number of Shares	Approximate percentage of shareholding in our total share capital	Number of Shares	Approximate percentage of shareholding in Unlisted Shares/H Shares ⁽¹⁾	Approximate percentage of shareholding in our total share capital ⁽¹⁾
Dr. Shen ⁽²⁾	Beneficial interest	82,461,110	54.97%	[REDACTED] Unlisted Shares (L)	[REDACTED]%	[REDACTED]%
	Interest of spouse	2,272,478	1.52%	[REDACTED] Unlisted Shares (L)	[REDACTED]%	[REDACTED]%
Ms. Jin Jie ⁽²⁾	Beneficial interest	2,272,478	1.52%	[REDACTED] Unlisted Shares (L)	[REDACTED]%	[REDACTED]%
	Interest of spouse	82,461,110	54.97%	[REDACTED] Unlisted Shares (L)	[REDACTED]%	[REDACTED]%
Dr. Tian	Beneficial interest	14,316,611	9.54%	[REDACTED] Unlisted Shares (L)	[REDACTED]%	[REDACTED]%
Suzhou Hesheng	Beneficial interest	6,783,346	4.52%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Mr. Qiao Gang ⁽³⁾	Interest in controlled corporations	5,402,703	3.60%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
	Interest held jointly with other persons	1,092,539	0.73%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Xieyao PE ⁽³⁾	Interest in controlled corporations	5,402,703	3.60%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
	Interest held jointly with other persons	1,092,539	0.73%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Xieyao Kexin ⁽³⁾	Beneficial interest	4,370,157	2.91%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
	Interest held jointly with other persons	2,125,085	1.42%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Xieyao Kesheng ⁽³⁾	Beneficial interest	1,032,546	0.69%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
	Interest held jointly with other persons	5,462,696	3.64%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of Interest	As of the Latest Practicable Date		Immediately following the [REDACTED] (assuming the [REDACTED] is not exercised)		
		Number of Shares	Approximate percentage of shareholding in our total share capital	Number of Shares	Approximate percentage of shareholding in Unlisted Shares/H Shares ⁽¹⁾	Approximate percentage of shareholding in our total share capital ⁽¹⁾
Shen Juan ⁽³⁾	Interest in controlled corporations	1,092,539	0.73%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
	Interest held jointly with other persons	5,402,703	3.60%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Zhao Hao ⁽³⁾	Interest in controlled corporations	1,092,539	0.73%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
	Interest held jointly with other persons	5,402,703	3.60%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Suzhou Meilingge ⁽³⁾	Beneficial interest	1,092,539	0.73%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
	Interest held jointly with other persons	5,402,703	3.60%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Ms. Jin Qing	Beneficial interest	5,517,145	3.68%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%
Zhongcai Qihu	Beneficial interest	4,370,157	2.91%	[REDACTED] H Shares (L)	[REDACTED]%	[REDACTED]%

Notes:

- (1) The calculation is based on the total number of [REDACTED] Unlisted Shares in issue and [REDACTED] H Shares in issue upon the completion of the [REDACTED] (assuming the [REDACTED] is not exercised) comprising (i) an aggregate of [REDACTED] H Shares to be converted from the Unlisted Shares and (ii) [REDACTED] H Shares to be issued pursuant to the [REDACTED] (assuming the [REDACTED] is not exercised).
- (2) Ms. Jin Jie is the spouse of Dr. Shen. As such, Dr. Shen and Ms. Jin Jie are deemed to be interested in Shares held by each other.
- (3) Xieyao Kexin, Xieyao Kesheng and Suzhou Meilingge are Pre-[REDACTED] Investors of the Company through directly holding 4,370,157 Shares, 1,032,546 Shares and 1,092,539 Shares, respectively. Xieyao Kexin, Xieyao Kesheng and Suzhou Meilingge are parties acting-in-concert in respect of the voting rights held in the Company. Therefore, Xieyao Kexin, Xieyao Kesheng and Suzhou Meilingge are deemed to be interested in the Shares held by each and every of them.

As of the Latest Practicable Date, Xieyao PE was the executive partner of each of Xieyao Kexin and Xieyao Kesheng, and Xieyao PE was ultimately controlled by Mr. Qiao Gang. Therefore, Mr. Qiao Gang and Xieyao PE are deemed to be interested in the Shares held or controlled by Xieyao Kexin and Xieyao Kesheng.

As of the Latest Practicable Date, the executive partner of Suzhou Meilingge was Shen Juan and the largest limited partner of Suzhou Meilingge was Zhao Hao, with the partnership interest as to 40%. Therefore, Shen Juan and Zhao Hao are deemed to be interested in the Shares held or controlled by Suzhou Meilingge.

SUBSTANTIAL SHAREHOLDERS

For details of the substantial shareholders who will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group other than our Company, see “Appendix VII — Statutory and General Information — C. Further Information about Our Directors, Supervisors and Substantial Shareholders — 2. Substantial Shareholders” in this document.

Save as disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), without taking into account the [REDACTED] that may be taken up under the [REDACTED], have interests or short positions in Shares or underlying Shares which would fall to be disclosed under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board of Directors consists of six Directors, including two executive Directors, one non-executive Director and three independent non-executive Directors. Our Board serves a term of three years and is responsible and has general powers for the management and conduct of our business.

The table below sets out certain information in respect of the members of the Board.

Name	Age	Position	Date of Appointment as Director	Date of joining our Group	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Dr. Tian Guanghui (田廣輝)	44	Chairman of the Board, executive Director, chief executive officer and general manager	June 28, 2020	January 21, 2013	Responsible for the overall strategic planning, business direction and operational management	None
Dr. Hu Tianwen (胡天文)	35	Executive Director and deputy general manager	June 20, 2023	August 19, 2022	Responsible for the management and R&D strategy	None
Mr. Liu Haoxuan (劉浩軒)	49	Non-executive Director	June 28, 2020	June 28, 2020	Responsible for overseeing the management and operation	None
Dr. Ju Dianwen (鞠佃文)	56	Independent non-executive Director	March 27, 2023	March 27, 2023	Responsible for supervising the corporate governance of our Company and providing independent opinion to our Board	None
Ms. Cao Xinwen (曹新文)	46	Independent non-executive Director	March 27, 2023	March 27, 2023	Responsible for supervising the corporate governance of our Company and providing independent opinion to our Board	None
Dr. Xu Hongxi (徐宏喜)	63	Independent non-executive Director	January 24, 2025	January 24, 2025	Responsible for supervising the corporate governance of our Company and providing independent opinion to our Board	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

The following sets forth the biographies of our Directors:

Executive Directors

Dr. Tian Guanghui (田廣輝), aged 44, is the chairman of the Board, executive Director, chief executive officer and general manager of our Company. Dr. Tian joined our Company in January 2013 as a chief executive officer and has been a Director and the general manager of our Company since June 28, 2020 and the chairman of the Board since June 14, 2023. He was redesignated as the executive Director in January 2025. He has been the director and the general manager of Vigonvita Lianyungang since December 2019; the director of Yingjiu Health since December 2023 and the director of Qingdao Antai since April 2024. Dr. Tian is primarily responsible for the overall organizational management and operation of our Group.

Dr. Tian has accumulated over 20 years of experience in the pharmaceutical industry. Prior to joining our Company, he worked as a manager at Yunnan Suwangrun Biopharmaceutical Co., Ltd. (雲南蘇旺潤生物醫藥有限公司) from September 2020 to September 2021. Dr. Tian served as a compositing director (合成總監) from August 2011 to December 2014 and worked as a laboratory manager from August 2007 to August 2008 at Topharman Shanghai, a pharmaceutical company specialized in R&D of active pharmaceutical ingredient.

Dr. Tian also served as a supervisor in Shanghai Wangshi Biomedical Technology Co., Ltd. (上海旺實生物醫藥科技有限公司) from December 2021 to March 2023.

Dr. Tian obtained his master’s degree and doctor’s degree in medicinal chemistry from Shanghai Institute of Materia Medica of the CAS (中國科學院上海藥物研究所) in the PRC in July 2007 and July 2011, respectively. He obtained his qualification as a senior engineer from the Jiangsu Provincial Department of Human Resources and Social Security (江蘇省人力資源和社會保障廳) in August 2019.

Dr. Hu Tianwen (胡天文), aged 35, is the executive Director and deputy general manager of our Company. He was appointed as a Director in June 2023 and deputy general manager of our Company in March 2023. He was redesignated as an executive Director in January 2025. He has been appointed as the general manager of Vigonvita Shanghai since August 2022 and as a director of Vigonvita Lianyungang since June 2023. Dr. Hu is mainly responsible for the management and R&D strategy of our Group.

Prior to joining our Group, Dr. Hu served as a researcher in Shanghai Topharman from July 2016 to September 2022.

Dr. Hu obtained his bachelor’s degree in pharmaceutical engineering from Wannan Medical College (皖南醫學院) in the PRC in July 2012. He then obtained his master’s degree in pharmacy from Shanghai Institute of Materia Medica of the CAS (中國科學院上海藥物研究所) in the PRC in July 2016. He further achieved his doctor’s degree in organic chemistry from Xinjiang Institute of Physics and Chemistry Technology of the CAS (中國科學院新疆理化技術研究所) in the PRC in June 2022.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Non-executive Director

Mr. Liu Haoxuan (劉浩軒), aged 49, is the non-executive Director of our Company. He was appointed as a Director in June 2020 and was redesignated as the non-executive Director in January 2025. He is mainly responsible for overseeing the management and operation of our Group.

Mr. Liu currently serves as an executive director and general manager of Yunnan Suwangrun Biopharmaceutical Co., Ltd. (雲南蘇旺潤生物醫學有限公司), a company primarily engaged in pharmaceutical production and wholesale, since September 2021.

Mr. Liu served as an executive director of Yunnan Langrun Biotechnology Co., Ltd. (雲南蕓潤生物科技有限公司), a company principally engaged in health products production and sale, from September 2020 to November 2024. Mr Liu also served as a supervisor at Xiangcheng County Lingshan Tourism Co., Ltd. (襄城縣靈山旅遊有限公司), a company engaged in tourism services, from February 2019 to April 2023. He served as a supervisor at Suzhou AlphaMa Biotechnology Co., Ltd. (蘇州阿爾脈生物科技有限公司), a company principally engaged in biomedicine R&D, from July 2018 to November 2023, and has been serving as a chairman of the board and general manager since November 2023. From May 2021 to February 2022, he served as an executive director and general manager of Hainan Jiukuzhen Technology Development Co., Ltd. (海南九庫甄科技發展有限公司). From December 2019 to October 2020, he served as an executive director at Yunnan Shengtai Biotechnology Co., Ltd. (雲南升泰生物科技有限公司), a company primarily engaged in R&D in biotechnology.

Independent non-executive Directors

Dr. Ju Dianwen (鞠佃文), aged 56, has been an independent director of our Company since March 27, 2023 and redesignated as independent non-executive Director of our Company since January 2025. He is mainly responsible for supervising the corporate governance of our Company and providing independent opinion to our Board.

Dr. Ju has been a researcher of Department of Biomedicines, School of Pharmacy at Fudan University (復旦大學) in the PRC since 2011. Before that, Dr. Ju had successively served as a teaching assistant and lecturer in the Department of Medical Immunology at the Second Military Medical University (中國人民解放軍第二軍醫大學) then as a deputy general manager at Shanghai MediPharm Biotech Co., Ltd. (上海美恩生物技術有限公司), where he was responsible for the R&D in innovative drugs.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Currently, Dr. Ju holds several positions in multiple companies, including (i) as a supervisor of Shanghai Dongci Biotechnology Co., Ltd. (上海東慈生物科技有限公司) since March 2019, (ii) as a scientific advisor of Novatim Immune Therapeutics (Zhejiang) Co., Ltd. (科奔(浙江)藥業科技有限公司) since October 2019, (iii) as a director of Xingshen Biotechnology (Hangzhou) Co., Ltd. (行深生物科技(杭州)有限公司) (previously known as Shanghai Xingshen Biotechnology Co., Ltd. (上海行深生物科技有限公司) since April 2020, (iv) as a director of Shanghai Xinze Venture Capital Management Co., Ltd. (上海莘澤創業投資管理股份有限公司) since December 2019, and (v) as an independent director of Shanghai Bao Pharmaceuticals Co., Ltd. (上海寶濟藥業股份有限公司). From April 2020 to December 2024, Dr. Ju served as an independent director at Shanghai Baolong Pharmaceutical Co., Ltd. (上海寶龍藥業股份有限公司).

Dr. Ju obtained his bachelor’s degree in pharmacy, master’s degree in medicine, and doctor’s degree in medical immunology from the Second Military Medical University (中國人民解放軍第二軍醫大學) in the PRC in July 1991, July 1994 and June 1999, respectively.

Ms. Cao Xinwen (曹新文), aged 46, has been an independent director of our Company since March 27, 2023 and redesignated as independent non-executive Director of our Company since January 2025. She is mainly responsible for supervising the corporate governance of our Company and providing independent opinion to our Board.

Ms. Cao has accumulated more than 18 years of experience in accounting and management.

Prior to joining our Company, Ms. Cao has been serving as a director of Jiangxi Tianyuan Environmental Protection Group Co., Ltd. (江西天沅環保集團股份有限公司), a company principally engaged in the R&D, production, and sales of fatty acid products from February 2018 to December 2024. She has been serving as the chief accountant of Shanghai Minxing Accounting Firm (上海民興會計師事務所) since February 2013 as well.

Ms. Cao was an executive director of Jiangsu Huifang Enterprise Management Consulting Co., Ltd. (江蘇慧芳企業管理諮詢有限公司), a company principally engaged in business management consulting and software development, and she was responsible for project management from January 2018 to October 2019. She also served as an audit manager at Zhonglei Accounting Firm Shanghai Branch (中磊會計師事務所上海分所) from December 2006 to February 2008. She worked as an auditor at Shanghai Jianxin Bada Accounting Firm (上海建信八達會計師事務所) from May 2003 to November 2006.

In addition, she served as an independent non-executive director at Zhejiang Jinsheng New Materials Co Ltd. (浙江錦盛新材料股份有限公司), an acrylic containers manufacturing company listed on the main board of the Shenzhen Stock Exchange (stock code: 300849) from November 2016 to November 2022.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Ms. Cao obtained her secondary vocational school diploma in financial accounting from Lianyungang Finance and Economics School (連雲港市財經學校) in the PRC in June 1996. She further obtained her bachelor’s degree in management studies majoring in accounting from Nanjing University of Finance and Economics (南京財經大學) in the PRC in March 2005 through self studies. Ms. Cao was qualified for intermediate accounting (會計中級) from the Ministry of Finance (財政部) of the PRC in May 2002 and possesses Chinese Certified Public Accountant Certificate.

Dr. Xu Hongxi (徐宏喜), aged 63, has been the independent non-executive Director of our Company since January 2025. He is mainly responsible for supervising the corporate governance of our Company and providing independent opinion to our Board.

Prior to joining our Group, Dr. Xu has been serving as a professor at the Shanghai University of Traditional Chinese Medicine (上海中醫藥大學) since December 2010. He was a deputy director at the Hong Kong Jockey Club Institute of Chinese Medicine (香港賽馬會中藥研究院) from October 2001 to November 2010. He served as a deputy general manager at Hutchison Whampoa (China) Limited (和記黃埔(中國)有限公司) from October 1999 to September 2001, and he was mainly responsible for the business related to Chinese medicines. He worked as a scientific officer at the Chinese Medicinal Material Research Centre of the Chinese University of Hong Kong (香港中文大學中藥研究中心) from September 1998 to September 1999. He served as a research associate at Dalhousie University in Canada from November 1996 to October 1997 and Department of Chemistry of National University of Singapore in Singapore from October 1994 to October 1996.

In addition, he has been serving as an independent non-executive director at Beijing Tong Ren Tang Chinese Medicine Company Limited (北京同仁堂國藥有限公司), a Chinese medicine manufacturing company listed on the Main Board of the Hong Kong Stock Exchange (stock code: 3613) since March 2023.

Dr. Xu obtained his bachelor’s degree and master’s degree in Chinese materia medica from the Shanghai University of Traditional Chinese Medicine (上海中醫藥大學) in the PRC in July 1983 and April 1989, respectively. Dr. Xu further obtained his Ph.D. degree in pharmaceutical science from the University of Toyama (日本富山醫學科大學) in Japan in March 1994. He received the title of “State Specially Recruited Experts” (國家特聘專家) from Organization Department of CCCPC (中共中央組織部) and Ministry of Human Resources and Social Security (人力資源和社會保障部).

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

General

Each of our Directors has confirmed that:

- (1) he/she obtained the legal advice referred to under Rule 3.09D of the Listing Rules in January 2025, and understood his/her obligations as a director of a [REDACTED];
- (2) save as disclosed in the paragraph headed “Appendix VII — Statutory and General Information — C. Further Information about Our Directors, Supervisors and Substantial Shareholders — 1. Disclosure of Interests” in this document, he/she has no interest in the Shares within the meaning of Part XV of the SFO as at the Latest Practicable Date;
- (3) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to and as at the Latest Practicable Date;
- (4) other than being a Director, he/she does not have any relationship with any other Directors, Supervisors, senior management or substantial Shareholders of our Company; and
- (5) he/she did not complete his/her education programs as disclosed in this section by way of attendance of long-distance learning or online courses.

Each of our independent non-executive Directors has confirmed:

- (1) his/her independence after taking into consideration each of the factors referred to under Rules 3.13(1) to 3.13(8) of the Listing Rules;
- (2) that he/she does not have any past or present financial or other interest in the business of our Company or our subsidiaries, or any connection with any core connected person of our Company; and
- (3) that there are no other factors which may affect his/her independence at the time of his/her appointment as our independent non-executive Director.

Save as disclosed in this document, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries:

- (1) there is no other matter with respect to the appointment of our Directors that needs to be brought to the attention to the Shareholders as of the Latest Practicable Date; and
- (2) there is no other information relating to our Directors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SUPERVISORY COMMITTEE

Our Supervisory Committee comprises three members. Our Supervisors serve a term of three years and may be re-elected for successive reappointments. The functions and duties of the Supervisory Committee include reviewing financial reports, business reports and profit distribution plans prepared by the Board and overseeing the financial and business performance of our Company. They are also entitled to appoint certified public accountants and practicing auditors to re-examine our Company’s financial information where necessary.

The following table sets out information in respect of the Supervisors.

Name	Age	Position	Date of Appointment as a Supervisor	Date of joining our Group	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Dr. Yang Rulei (楊汝磊)	38	Chairman of the Supervisory Committee	September 15, 2021	September 18, 2016	Responsible for monitoring and supervising the operation of the Company, and performing other supervisory duties	None
Mr. Zhou Hongju (周洪舉)	46	Supervisor	September 15, 2021	September 15, 2021	Responsible for supervising our Board and senior managements and performing other supervisory duties as a Supervisor	None
Mr. Li Jian (李建)	42	Supervisor (employee’s representative)	March 15, 2021	December 1, 2013	Responsible for performing other supervisory duties as a Supervisor.	None

Dr. Yang Rulei (楊汝磊), aged 38, is the Chairman of Supervisory Committee. He joined our Company as the director of the formulation department in September 2016 and is mainly responsible for overseeing the formulation department. Since September 2021, Dr. Yang has been appointed as the Chairman of our Supervisory Committee and is primarily responsible for monitoring and supervising the operation of the Company and performing other supervisory duties as a Supervisor.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Prior to joining our Company, Dr. Yang worked as a production manager at Shanghai Wangshi Biomedical Technology Co., Ltd. (上海旺實生物醫藥科技有限公司), a company principally engaged in biomedicine R&D from April 2022 to February 2023. He served as a senior manager of formulation department at Suzhou Suncadia Biopharmaceutical Co., Ltd. (蘇州盛迪亞生物醫藥有限公司), a subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江蘇恒瑞醫藥股份有限公司) (a company listed on the Shanghai Stock Exchange (stock code: 600276.SH)), from March 2020 to May 2020. Dr. Yang worked at Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (正大天晴藥業集團股份有限公司) and Suzhou Kelun Pharmaceutical Research Co., Ltd. (蘇州科倫藥物研究有限公司) from August 2012 to March 2015 and April 2015 to September 2016, respectively.

Dr. Yang obtained his bachelor’s degree in pharmaceutical engineering from Wuhan University of Technology (武漢理工大學) in the PRC in June 2009. He further obtained his master’s degree in pharmacy from Tianjin University (天津大學) in the PRC in June 2012. He obtained his doctor’s degree in Chinese medicines from Nanjing University of Chinese Medicine (南京中醫藥大學) in the PRC in September 2024. Dr. Yang is qualified as a senior engineer from the Jiangsu Provincial Department of Human Resources and Social Security (江蘇省人力資源和社會保障廳) in December 2021.

Mr. Zhou Hongju (周洪舉), aged 46, has been appointed as a Supervisor since September 2021. He is mainly responsible for supervising our Board and senior managements and performing other supervisory duties as a Supervisor.

Mr. Zhou has been working at Zhongcai Financial Holding Investment Co., Ltd. (中財金控投資有限公司) since March 2020. He also worked at (i) China International Intellectech Group Co., Ltd. (中國國際技術智力合作集團有限公司) from March 2017 to February 2020, (ii) Beijing Xinkun Guotai Investment Management Co., Ltd (北京鑫坤國泰投資管理有限公可) from January 2016 to February 2017, (iii) Beijing Hongma Tian’an Investment Co. Ltd. (北京紅馬天安投資有限公司) from July 2015 to December 2015, (iv) Dexinhui (Beijing) Investment Management Co., Ltd. from September 2013 to March 2015, (v) China International Intellectech Group Co., Ltd. (中國國際技術智力合作集團有限公司) from December 2009 to July 2013, (vi) Beijing Gabriel Consulting Co., Ltd. (北京美加百利諮詢有限公司) from April 2009 to August 2009 and (vii) Beijing Kewei Computer Co., Ltd. (北京市可為電腦有限公司) from January 2008 to January 2009.

Mr. Zhou obtained his master’s degree in law from Central University of Finance and Economics (中央財經大學) in the PRC in January 2015. He obtained the Legal Professional Qualification Certificate of the People’s Republic of China in February 2005.

Mr. Li Jian (李建), aged 42, is an employee’s representative Supervisor. He has joined our Company as a senior researcher of organic synthesis since December 2013, and was appointed as a supervisor of our Company in March 2021. He is primarily responsible for performing other supervisory duties as a Supervisor.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Prior to joining our Company, he has been serving as a supervisor at Shanghai Synmedia Chemical Co., Ltd. (上海三牧化工技術有限公司) since 2009, a company principally engaged in bulk chemical sales. From May 2022 to February 2023, he worked as a principal researcher at Suzhou Abogen Biosciences Co., Ltd. (蘇州艾博生物科技股份有限公司), a biotech company, and he was mainly responsible for chemical synthesis. Mr. Li worked as an associate researcher at Ascepcion Pharmaceuticals Inc. (蘇州愛斯鵬藥物研發有限責任公司), a company primarily engaged in drug R&D, from November 2012 to May 2013. He served as a team coordinator at AnRun Medical Technology (Suzhou) Co., Ltd. (安潤醫藥科技(蘇州)有限公司) from August 2011 to July 2012. He worked as a researcher at WuXi AppTec Co., Ltd. (無錫藥明康德新藥開發股份有限公司), a company listed on the Main Board of the Stock Exchange (stock code: 2359.HK) and the Shanghai Stock Exchange (stock code: 603259.SH), from June 2008 to June 2011.

Mr. Li graduated from Yantai University (煙臺大學) in the PRC in July 2004 majoring in biotechnology. He further obtained his master’s degree in biochemical engineering from Zhejiang University of Technology (浙江工業大學) in the PRC in June 2008.

General

Each of our Supervisors has confirmed that:

- (1) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to and as at the Latest Practicable Date;
- (2) other than being a Supervisor, he/she does not have any relationship with any other Directors, Supervisors, senior management or substantial Shareholders of our Company; and
- (3) he/she did not complete his/her education programs as disclosed in this section by way of attendance of long distance learning or online courses.

Save as disclosed in this document, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries:

- (1) there is no other matter with respect to the appointment of our Supervisors that needs to be brought to the attention to the Shareholders as of the Latest Practicable Date; and
- (2) there is no other information relating to our Supervisors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management and operation of our business. The table below sets out certain information in respect of the senior management of our Group.

Name	Age	Position	Date of Appointment as a senior management	Date of joining our Group	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Dr. Tian Guanghui (田廣輝)	44	Chairman of the Board, executive Director, and general manager	January 21, 2013	January 21, 2013	Responsible for the overall strategic planning, business direction and operational management	None
Dr. Hu Tianwen (胡天文)	35	Executive Director and deputy general manager	March 27, 2023	August 19, 2022	Responsible for the management and R&D strategy	None
Mr. Wang Zhiqiang (王志強)	49	Deputy general manager	May 23, 2022	May 23, 2022	Responsible for the supervision and execution of clinical trials	None
Ms. Guo Ting (郭婷)	41	Secretary of the Board and joint company secretary	August 31, 2022	August 31, 2022	Responsible for the financing and capital operation	None
Ms. Yao Zheng (藥箏)	40	Financial controller	July 11, 2022	July 11, 2022	Responsible for overseeing the financial management and investment	None

Dr. Tian Guanghui (田廣輝), see “— Board of Directors — Executive Directors” in this section for details.

Dr. Hu Tianwen (胡天文), see “— Board of Directors — Executive Directors” in this section for details.

Dr. Wang Zhiqiang (王志強), aged 49, joined our Company as the deputy general manager in May 2022. He is primarily responsible for the supervision and execution of clinical trials.

Prior to joining our Group, Dr. Wang had been working at Nanjing Sanhome Pharmaceutical Co. Ltd. (南京聖和藥業股份有限公司) (previously known as Nanjing Sanhome Pharmaceutical Ltd. (南京聖和藥業有限公司)), a company principally engaged in pharmaceutical production, for more than 20 years, taking up various roles and responsibilities. Dr. Wang served as (i) an assistant to the general manager, vice president of the research institute, director of the clinical medicine center and the head of the registration department

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

from September 2021 to May 2022; (ii) a director of clinical medicine center from January 2015 to September 2021; (iii) an assistant to the dean, director of pharmacology office and head of clinical department from January 2013 to December 2014; (iv) an assistant to the dean and director of the pharmacology and clinical office from June 2008 to December 2012; (v) an assistant to the head of R&D department and manager of the analysis office from July 2003 to June 2008; (vi) a project manager from January 2001 to June 2003; and (vii) a researcher from August 2000 to January 2001.

Dr. Wang obtained his bachelor’s degree in pharmacology from China Pharmaceutical University (中國藥科大學) in the PRC in July 2000. He obtained his master’s degree in pharmaceutical engineering from Nanjing University (南京大學) in the PRC in June 2011. He further obtained his doctor’s degree in pharmacology from China Pharmaceutical University in June 2021. Dr. Wang obtained his qualification as a professor level senior engineer from the Jiangsu Provincial Department of Human Resources and Social Security (江蘇省人力資源和社會保障廳) and Suzhou Municipal Department of Human Resources and Social Security (蘇州市人力資源和社會保障局) in August 2023. He is a licensed pharmacist certified by the Jiangsu Provincial Department of Human Resources and Social Security (江蘇省人事廳) since April 2004.

Ms. Guo Ting (郭婷), aged 41, is the secretary of the Board of our Company. She joined our Company in August 2022 and has been appointed as the joint company secretary in January 2025, and is mainly responsible for the financing and capital operation.

Prior to joining our Group, Ms. Guo served as a secretary of the board at Sinopep Allsino Bio Pharmaceutical Co., Ltd. (江蘇諾泰澳賽諾生物製藥股份有限公司) from September 2015 to August 2022, a company listed on the Shanghai Stock Exchange (stock code: 688076.SH). She served as a department manager at Zhongyi Group Co., Ltd. (中毅集團有限公司) from July 2011 to August 2015, a company principally engaged in real estate investments. Ms. Guo served as a department head at Focused Photonics (Hangzhou), Inc. (聚光科技(杭州)股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 300203.SZ) from January 2007 to June 2011, where she was primarily responsible for sales management.

Ms. Guo obtained her bachelor’s degree in optical information science and technology from Chongqing University of Posts and Telecommunications (重慶郵電大學) in the PRC in July 2005. She further obtained her master’s degree in business administration from Zhejiang University (浙江大學) in the PRC in December 2012. She has been pursuing her doctor’s degree in business administration from Lyon University through part-time learning since 2022. Ms. Guo obtained the certificate of senior international finance manager from the Ministry of Human Resources and Social Security of the PRC (中國人力資源和社會保障部) on May 26, 2016 and the certificate of senior carbon emission reduction manager from China Energy Conservation Association (中國節能協會) on May 22, 2023. She is also qualified as a senior economist by Shanghai Municipal Human Resources and Social Security Bureau (上海市人力資源和社會保障局) on December 24, 2023. Ms. Guo obtained the certificate of board secretary by (i) Shanghai Stock Exchange in May 2015 and (ii) Shenzhen Stock Exchange in October 2016.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Ms. Yao Zheng (藥箏), aged 40, is the financial controller of our Company. She joined our Company in July 2022. She has appointed as the financial controller of Qingdao Antai in April 2024. She is mainly responsible for overseeing the financial management and investment.

Prior to joining our Company, Ms. Yao served as a financial director at Taizhou EOC Pharma Co., Ltd. (泰州億騰景昂藥業股份有限公司) from November 2019 to June 2022. She also served as a financial director at Shanghai Purity Media Co., Ltd. (上海千足文化傳播有限公司) from February 2017 to October 2019. From June 2011 to June 2015, Ms. Yao worked as an audit manager at Evergreen Group Co., Ltd. (春和集團有限公司). She worked as an auditor at Shanghai branch of Ernst & Young from August 2006 to May 2011.

Ms. Yao obtained her bachelor’s degree in international auditing from Nanjing Audit University (南京審計大學) in the PRC in June 2006. She further obtained her master’s degree in business administration from the China Europe International Business School (中歐國際工商學院) in the PRC in April 2017. She is admitted as a member of the Association of Chartered Certified Accountants since October 2009 and is certified as a Certified Internal Auditor by the Institute of Internal Auditors since November 2011.

General

Save as disclosed above, each of our senior management members has confirmed that:

- (1) he/she does not hold any other positions in our Company as at the Latest Practicable Date;
- (2) save as being a Director and/or a member of the Company’s senior management, he/she does not have any other relationship with any Directors, Supervisors, substantial shareholders or other members of senior management of our Company as at the Latest Practicable Date;
- (3) he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to the Latest Practicable Date and as at the Latest Practicable Date; and
- (4) he/she has not completed his/her education programs as disclosed in this section by way of attendance of long-distance learning or online courses.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

JOINT COMPANY SECRETARIES

Ms. Guo Ting (郭婷), see “— Senior Management” in this section for details.

Ms. Au Wing Sze (區詠詩) was appointed as our joint company secretary of the Company in January 2025. Ms. Au is a manager of the listing services department of TMF Hong Kong Limited and has been providing corporate secretarial and compliance services to Hong Kong listed companies. She has over 10 years of working experience in company secretarial profession. Ms. Au is an associate of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom. Ms. Au holds a master degree in corporate governance from Hong Kong Metropolitan University.

COMPLIANCE ADVISER

We have appointed Somerley Capital Limited as our compliance adviser pursuant to Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the compliance adviser will advise us on the following circumstances:

- before the publication of any regulatory announcements, circulars or financial reports;
- where a transaction, which might be a notifiable or connected transaction under Chapters 14 and 14A of the Listing Rules is contemplated, including share issues, sales or transfers of treasury shares and share repurchases;
- where our Company proposes to use the [REDACTED] from the [REDACTED] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry of our Company regarding unusual price movement and trading volume or other issues under Rule 13.10 of the Listing Rules.

The terms of the appointment shall commence on the [REDACTED] and end on the date which we distribute our annual report of our financial results for first full the financial year commencing after the [REDACTED].

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD COMMITTEES

Our Company has established the following committees on our Board: an audit committee, a remuneration and appraisal committee, and a nomination committee. The committees operate in accordance with the terms of reference established by our Board.

Audit Committee

Our Company has established an audit committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of Part 2 of the Corporate Governance Code set out in Appendix C1 to the Listing Rules. The audit committee consists of one non-executive Director and two independent non-executive Directors, namely Ms. Cao Xinwen, Dr. Xu Hongxi and Dr. Ju Dianwen, with Ms. Cao Xinwen serving as the chairperson. Ms. Cao Xinwen holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the audit committee are to assist our Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of our Company, overseeing the audit process, and performing other duties and responsibilities as assigned by our Board.

Remuneration and Appraisal Committee

Our Company has established a remuneration and appraisal committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of Part 2 of the Corporate Governance Code set out in Appendix C1 to the Listing Rules. The remuneration and appraisal committee comprises one executive Director and two independent non-executive Director, namely, Dr. Xu Hongxi, Dr. Hu Tianwen and Dr. Ju Dianwen, with Dr. Xu Hongxi serving as the chairperson. The primary duties of the remuneration and appraisal committee include, but are not limited to, the following: (i) making recommendations to our Board on our policy and structure for all remuneration of Directors and senior management and on the establishment of a formal and transparent procedure for developing policy on such remuneration; (ii) determining the specific remuneration packages of all Directors and senior management; and (iii) reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by our Board from time to time.

Nomination Committee

Our Company has established a nomination committee with written terms of reference in compliance with Rule 3.27A of the Listing Rules and paragraph B.3 of Part 2 of Corporate Governance Code set out in Appendix C1 to the Listing Rules. The nomination committee comprises one executive Directors and two independent non-executive Directors, namely Dr. Tian, Dr. Xu Hongxi and Ms. Cao Xinwen, with Dr. Tian serving as the chairperson. The primary duties of the nomination committee include, without limitation, reviewing the structure, size and composition of our Board, assessing the independence of independent non-executive Directors and making recommendations to our Board on matters relating to the appointment of Directors.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

CORPORATE GOVERNANCE CODE

Our Company is committed to achieving high standards of corporate governance with a view to safeguarding the interests of our Shareholders. To accomplish this, our Company intends to comply with Corporate Governance Code set out in Appendix C1 to the Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules after the [REDACTED].

Pursuant to paragraph C.2.1 of Part 2 of the Corporate Governance Code, companies listed on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities between chairman and chief executive should be segregated and should not be performed by the same individual. We do not have a separate chairman and chief executive and Dr. Tian currently performs the roles of the chairman of the Board, executive Director, chief executive officer and general manager of our Company. Dr. Tian has assumed the role of chief executive officer of our Company since January 2013. He has extensive experience in the business operations and management of our Group. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned above, Dr. Tian is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our general manager. The Board also believes that vesting the roles of both chairman and general manager in the same person has the benefit of (i) ensuring consistent leadership within the Group, (ii) enabling more effective and efficient overall strategic planning and execution of strategic initiatives of the Board, and (iii) facilitating the flow of information between the management and the Board for the Group. The Board considers that the balance of power and authority for the present arrangement will not be impaired, and this arrangement will enable the Company to make and implement decisions promptly and effectively. The Board will continue to review and consider splitting the roles of chairman of the Board and general manager of the Company at a time when it is appropriate by taking into account the circumstances of the Group as a whole.

Save as disclosed above, our Directors consider that upon [REDACTED], we will comply with all applicable code provisions of the Corporate Governance Code as set out in Appendix C1 to the Listing Rules.

BOARD DIVERSITY

We have adopted a board diversity policy (the “**Board Diversity Policy**”) to enhance the effectiveness of our Board and to maintain a high standard of corporate governance. Pursuant to the Board Diversity Policy, in reviewing and assessing suitable candidates to serve as a Director, the nomination committee of our Company will consider a range of diversity perspectives with reference to our Company’s business model and specific needs, including but not limited to gender, age, language, cultural and educational background, professional qualifications, skills, knowledge, industry and regional experience and/or length of service.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Our Directors have a balanced mixed of knowledge and skills, including but not limited to finance and accounting, research and development, and investment. They obtained degrees in various majors including pharmaceutical engineering, medicinal chemistry, law, accounting, etc. Furthermore, our Board has a relatively wide range of ages, ranging from 35 years old to 63 years old and consists of five male members and one female member. The Board of Directors is of the view that our Board satisfies the Board Diversity Policy.

The nomination committee of our Company is responsible for reviewing the diversity of the Board, reviewing the Board Diversity Policy from time to time, developing and reviewing measurable objectives for implementing the Board Diversity Policy, and monitoring the progress on achieving these measurable objectives in order to ensure that the policy remains effective. Our Company will (i) disclose the biographical details of each Director and (ii) report on the implementation of the Board Diversity Policy (including whether we have achieved board diversity) in its annual corporate governance report. Our Company also intends to promote gender diversity when recruiting staff at the mid to senior level so that our Company will have a pipeline of female senior management and potential successors to the Board. We believe that such merit-based selection process with reference to our diversity policy and the nature of our business will be in the best interests of our Company and our Shareholders as a whole.

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, neither he/she or any of his/her close associates has any interest in a business which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract and (ii) a confidentiality agreement with our senior management members and other key personnel (other than Directors). Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

Confidentiality

- *Confidentiality obligations.* The employee shall, during the course of employment with our Company and thereafter, keep in confidence all technical, operational information or trade secrets belonging to our Company or other third parties to whom our Company owes confidentiality obligations. Without our Company's prior consent, the employee shall not leak, disclose, publish, announce, issue, teach, transfer or otherwise make available to any third party (including employees who are not privy to such trade secrets) any such trade secrets of our Company or the aforementioned third parties in any manner and shall not utilize such trade secret beyond his or her scope of work.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Non-competition

- *Non-competition obligation during employment term.* During the term of his/her employment with our Company, unless with our Company’s prior consent, the employee shall not engage in any business that competes with or are similar to that of our Company’s business.

Ownership of intellectual property rights

- *Acknowledgement.* The employee acknowledges and agrees that our Company shall own all intellectual property rights in any invention, work or non-patent technical result that is produced by him or her during the course of employment with our Company for the purposes of undertaking their duties and responsibilities.

Compensation for breach of covenants

- If the employee breaches the obligations under the confidentiality and intellectual property covenant, our Company shall be entitled to recover from the employee any losses incurred by the employee as a result of the breaches.

COMPENSATION OF DIRECTORS, SUPERVISORS AND MANAGEMENT

Our Directors, Supervisors and senior management receive compensation in the form of salaries and other benefits, retirement benefits scheme contribution, discretionary bonus and share-based payments. Our Directors’ remuneration is determined with reference to the relevant Director’s experience and qualifications, level of responsibility, performance and the time devoted to our business, and the prevailing market conditions.

The aggregate amount of remuneration of our Directors and Supervisors (including director fee, salaries and other benefits, discretionary bonuses, retirement benefit scheme contributions and share-based payments) which was recorded for the year ended December 31, 2023 and nine months ended September 30, 2024 were approximately RMB17.3 million and RMB13.1 million, respectively.

Under the arrangements currently in force, the aggregate amount of remuneration (including salaries and other benefits, retirement benefits scheme contribution, discretionary bonus and share-based payments) payable by our Company to our Directors and Supervisors for the financial year ending December 31, 2025 is expected to be approximately RMB36.8 million.

The five highest paid employees during the year ended December 31, 2023 and nine months ended September 30, 2024 included one and one Directors, respectively, and the aggregate amount of remuneration (including salaries and other benefits, retirement benefits scheme contribution, discretionary bonus and share-based payments) which were paid by our Group to the five highest paid employees who are neither a director nor chief executive of our Company were approximately RMB4.8 million and RMB3.5 million, respectively.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

During the Track Record Period, (i) no remuneration was paid to our Directors, Supervisors or the five highest paid individuals as an inducement to join, or upon joining our Company, (ii) no compensation was paid to, or receivable by, our Directors, past Directors, Supervisors, past Supervisors, or the five highest paid individuals for the loss of office as director of any member of our Group or any other office in connection with the management of the affairs of any member of our Group, and (iii) there was no arrangement under which a Director or Supervisor has waived or agreed to waive any emoluments.

Except as disclosed above, no other payments have been paid, or are payable, by our Group to our Directors, Supervisors or the five highest paid individuals of our Group during the Track Record Period.

For additional information on Directors’ and Supervisors’ remuneration during the Track Record Period as well as information on the highest paid individuals, see Note 13 to the “Appendix IA — Accountants’ Report” in this document.

FINANCIAL INFORMATION

The following discussion and analysis should be read in conjunction with the consolidated financial information together with the accompanying notes in the Accountants’ Report included in Appendix IA and the unaudited financial information for the nine months ended September 30, 2024 included in Appendix IB to this document. Our historical financial information and the consolidated financial statements of our Group have been prepared in accordance with the IFRSs, which may differ in certain material aspects from generally accepted accounting principles in other jurisdictions. You should read the whole Appendix IA and Appendix IB and not rely merely on the information contained in this section. Unless the context otherwise requires, historical financial information in this section is described on a consolidated basis.

The discussion and analysis set forth in this section contains forward-looking statements that involve risks and uncertainties. These statements are based on assumptions and analyses made by us in light of our experience and perception of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. Our actual results may differ significantly from those projected. Factors that could cause or contribute to such differences include, without limitation, those discussed in the sections headed “Risk Factors” and “Business” and elsewhere in this document. Discrepancies between totals and sums of amounts listed in this section in any table or elsewhere in this document may be due to rounding.

OVERVIEW

Founded in 2013, we are a fully-integrated biopharmaceutical company dedicated to the discovery, development and commercialization of innovative small molecule drugs. With mission to innovate for better health and quality of life, we strive to address the diverse and evolving patient needs in our strategically focused therapeutic areas, namely, (i) viral infection, (ii) neuropsychiatry and (iii) reproductive health. Over the past 12 years, we have not only established end-to-end capabilities spanning the entire industry value chain from research and clinical development to manufacturing and commercialization, but also developed a distinguished innovative pipeline of nine innovative assets, including three Core Products, VV116, LV232 and TPN171 each with first- or best-in-class potential.

During the Track Record Period, we generated revenue primarily from our out-licensing of VV116, provision of CRO services, as well as sales of pharmaceutical products. In 2023 and the nine months ended September 30, 2023 and 2024, we recorded revenue of RMB199.7 million, RMB194.4 million and RMB10.0 million, respectively. We recorded a net profit of RMB6.4 million in 2023, a net profit of RMB42.4 million for the nine months ended September 30, 2023, and a net loss of RMB156.4 million for the nine months ended September 30, 2024, respectively.

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We expect to incur a significant amount of operating expenses in the near term as we advance our pre-clinical research, continue the clinical development of, and seek regulatory approval for, manufacture and launch, our drug candidates, and recruit more talent necessary for the expansion of our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a public company. We expect that our financial performance may fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialization of our drug candidates.

MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which are outside of our control, including the following.

General Factors

Our business and operating results are affected by general factors affecting the global and China small molecule drug market, which include:

- relevant laws and regulations, governmental policies and initiatives affecting the global and China pharmaceutical industry;
- growth and competition environment of the global and China pharmaceutical industry, and in particular, the therapeutic areas we focus on; and
- political, economic and social evolvments of different local markets.

Company Specific Factors

Our Ability to Successfully Develop and Commercialize Our Drug Candidates

Our business and results of operations are dependent on our ability to successfully obtain necessary regulatory approval for and commercialize our drug candidates. As of the Latest Practicable Date, we have built a robust pipeline of innovative assets centered around our strategically focused three therapeutic areas, consisting of two in commercial or near-commercial stage, four in clinical stage and three in preclinical stage. In addition to our innovative pipeline, we have established a generic portfolio, including three drugs in commercial or near-commercial stage. For more details, see “Business.” In 2023 and the nine months ended September 30, 2023 and 2024, we generated revenue from the royalty payments in connection with the sales of VV116 in the PRC of RMB11.8 million, RMB11.7 million and RMB5.4 million, respectively, and from our sales of pharmaceutical products, including the sales of our generic drug, dapoxetine in the PRC and the sales of pharmaceutical products in Uzbekistan, of RMB0.7 million, RMB0.7 million and RMB0.6 million, respectively.

FINANCIAL INFORMATION

We expect that our revenue will continue to grow along with our enhanced marketing and promotion efforts for our commercialized products, our ongoing investments in research and development to advance clinical-stage drug candidates and expand therapeutic indications, as well as our endeavors to develop and commercialize additional drug candidates in the future. Upon commercialization of our drug candidates, our business and operations will be driven by the market acceptance and sales performance of the commercialized drugs, as well as our manufacturing capacity to meet commercial demands. Failure to achieve sufficient market acceptance could hinder our ability to generate the expected revenue.

Our Cost Structure

Our results of operations are significantly affected by our cost structure, particularly research and development expenses, administrative expenses, as well as selling expenses.

Research and development activities are central to our business model. During the Track Record Period, our research and development expenses consisted of (i) trial and testing expenses for our drug candidates; (ii) employee benefit expenses relating to salaries, bonus and other welfare for our research and development personnel; (iii) depreciation and amortization expenses in relation to our property, plant and equipment as well as intangible assets which were used for research and development purpose; (iv) utilities and office expenses incurred for our research and development activities; (v) material costs incurred in the course of our R&D activities; and (vi) others, mainly comprising traveling expenses of our research and development personnel, and other miscellaneous expenses. In 2023 and the nine months ended September 30, 2023 and 2024, our research and development expenses amounted to RMB131.3 million, RMB102.0 million, and RMB100.5 million, respectively.

Our current research and development activities mainly relate to the clinical advancement of our drug candidates. We expect our research and development costs to continue to increase for the foreseeable future as we move these drug candidates, either from preclinical studies to clinical trials, or further to more advanced clinical trials, and as we continue to support the clinical trials of our drug candidates as treatments for additional indications.

During the Track Record Period, our administrative expenses consisted of (i) employee benefits expenses mainly relating to salaries, bonus and other welfare for our administrative personnel; (ii) share-based compensation expenses, in connection with the restricted shares granted to our key management; (iii) depreciation and amortization related to assets for office and general purposes; (iv) professional service fees paid to legal advisors, auditors, and other consultants; (v) utilities and office expenses incurred for our administrative purpose; and (vi) others, mainly including tax and surcharges, travelling expenses and other miscellaneous expenses. In 2023 and the nine months ended September 30, 2023 and 2024, our administrative expenses amounted to RMB51.2 million, RMB39.4 million, and RMB50.9 million, respectively.

FINANCIAL INFORMATION

In addition to the research and development expenses and administrative expenses, we also anticipate that our selling expenses will increase as we continue to expand sales of our commercialized drugs and prepare for the commercialization of our drug candidates. During the Track Record Period, our selling expenses consisted of (i) employee benefits expenses, mainly relating to salaries, bonus and other welfare for our in-house selling and marketing personnel; (ii) marketing, promotion and advertising expenses; (iii) office expenses incurred for our selling and marketing activities; and (iv) others, mainly including depreciation and amortization expenses and other miscellaneous expenses. In 2023 and the nine months ended September 30, 2023 and 2024, our selling expenses amounted to RMB1.3 million, RMB0.8 million, and RMB2.9 million, respectively.

We expect our cost structure to evolve as we continue to develop and expand our business. As the clinical trials of our drug candidates continue to progress and as we continue to enrich our pipeline, we expect to incur additional costs in relation to preclinical and clinical studies, raw materials procurements, headcount expansion, among other things. Additionally, we anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong.

Funding for Our Operations

During the Track Record Period, we primarily funded our operations through a combination of equity and debt financing, supplemented by cash generated from operations. Going forward, as we continue to expand our business and advance the development and commercialization of our drug candidates, we expect to fund our operations primarily through revenue generated from the sales of our commercialized products and out-licensing arrangements, existing cash and cash equivalents, bank loans, and net [REDACTED] from the [REDACTED].

However, with the continuing growth of our business and expansion of our pipeline, additional funding may be required through public or private equity offerings, debt financing, or other sources. Any changes in our ability to secure adequate funding could impact our cash flow and overall financial performance.

BASIS OF PREPARATION

The historical financial information has been prepared based on the accounting policies set out in Note 4 to the Accountants’ Report set out in Appendix IA to the document, which conform with the International Financial Reporting Standards, or IFRSs issued by the International Accounting Standards Board, or IASB. In the preparation of the historical financial information, we have consistently applied the accounting policies which conform with IFRSs, which are effective for the accounting period beginning on January 1, 2024 throughout the Track Record Period and in the period covered by the interim comparative financial information. The historical financial information has been prepared on the historical cost basis except for certain financial instruments which are measured at fair values at the end of each of the Track Record Period.

The historical financial information is presented in RMB and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

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MATERIAL ACCOUNTING POLICIES, CRITICAL ACCOUNTING JUDGMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

Material Accounting Policies

Revenue Recognition

Out-licensing income

From 2021 to 2023, we entered into an out-licensing agreement and several supplementary agreements with customers to grant them (i) an exclusive right of research and development, production, and commercialization of VV116 for the treatment of COVID-19 and (ii) exclusive rights as the API provider for VV116 for the treatment of COVID-19 globally, except for five countries in Central Asia (i.e., Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (i.e., Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (i.e., Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan) and Russia (“granted regions”).

The consideration for the out-licensing comprises of (i) development milestones payments, (ii) royalties calculated based on the higher of revenue or gross profits as defined in the related supplementary agreement with customers, and (iii) an consideration for the exclusive rights as the API provider for VV116 for the treatment of COVID-19 in the granted regions.

The fee for the exclusive rights as the API provider for VV116 for the treatment of COVID-19 in the granted regions is recognized as revenue when the control of the supply right is obtained by the customer. Installment payment of total consideration was settled within one year after control of the supply right transferred. We apply the practical expedient of not adjusting the transaction price for any significant financing component.

For variable consideration in relation to milestone payments and royalties from out-licensing agreement, we estimate the amount of consideration to which we will be entitled using the most likely amount, which best predicts the amount of such consideration. The potential milestone payments that we are eligible to receive were considered as variable consideration as all milestone amounts were fully constrained due to uncertainty of achievement. The estimated amount of variable consideration is included in the transaction price only to the extent that it is highly probable that such an inclusion will not result in a significant revenue reversal in the future when the uncertainty associated with the variable consideration is subsequently resolved.

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At the end of each reporting period, we update the estimated transaction price (including updating its assessment of whether an estimate of variable consideration is constrained) to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period.

CRO services

Historically, we earned revenues by providing CRO services to our customers through fee-for-service (“FFS”) contracts. We carry out several research services including managing pre-clinical studies and preparing relevant application documents for our customers to ensure the research meet all regulatory guidelines. We identify all services as our performance does not create an asset with an alternative future use since we cannot redirect the asset for use on another customer, and the contract terms specify we have an enforceable right to payment for performance completed to date. And we use the input method to determine the progress of performance based on the percentage of costs incurred to date to the total estimated costs for the completion of the performance obligation.

The transaction price received by us is recognized as a contract liability until the services have been delivered to the customers.

Sales of pharmaceutical products

Revenue is recognized when control of the goods has been transferred, being when the goods have been delivered to the customers’ specific locations and the customers have inspected and accepted the goods. Transportation and handling activities that occur before customers obtain control are considered as fulfilment activities. A receivable is recognized by us when the control of goods are transferred to the customers. The normal credit term is typically 30 to 60 days upon the control of goods are transferred to the customers. The transaction price received by us is recognized as a contract liability until the control of goods are transferred to the customers.

Property, Plant and Equipment

Property, plant and equipment are tangible assets that are held for use in the production or supply of goods or services, or for administrative purposes other than construction in progress as described below are stated in the consolidated statement of financial position at cost less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

FINANCIAL INFORMATION

Property, plant and equipment in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management, including costs of testing whether the related assets are functioning properly and, for qualifying assets, borrowing costs capitalized in accordance with our accounting policy. Depreciation of these assets, on the same basis as other property assets, commences when the assets are ready for their intended use.

Depreciation is recognized so as to write off the cost of assets other than properties under construction less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

Leases

We assess whether a contract is or contains a lease based on the definition under IFRS 16 at inception of the contract. Such contract will not be reassessed unless the terms and conditions of the contract are subsequently changed.

Our Group as a lessee

Allocation of consideration to components of a contract

For a contract that contains a lease component and one or more additional lease or non-lease components, we allocate the consideration in the contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

Non-lease components are separated from lease component and are accounted for by applying other applicable standards.

Short-term leases and leases of low-value assets

We apply the short-term lease recognition exemption to leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option. It also applies the recognition exemption for lease of low-value assets. Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis or another systematic basis over the lease term.

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Right-of-use assets

The cost of right-of-use assets includes:

- the amount of the initial measurement of the lease liability; and
- any lease payments made at or before the commencement date, less any lease incentives received.

Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

Right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

We present right-of-use assets as a separate line item on the consolidated statement of financial position.

Refundable rental deposits

Refundable rental deposits paid are accounted under IFRS 9 and initially measured at fair value. Adjustments to fair value at initial recognition are considered as additional lease payments and included in the cost of right-of-use assets.

Lease liabilities

At the commencement date of a lease, we recognize and measure the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, we use the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable.

After the commencement date, lease liabilities are adjusted by interest accretion and lease payments.

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We remeasure lease liabilities (and makes a corresponding adjustment to the related right-of-use assets) whenever:

- the lease term has changed or there is a change in the assessment of exercise of a purchase option, in which case the related lease liability is remeasured by discounting the revised lease payments using a revised discount rate at the date of reassessment.
- a lease contract is modified and the lease modification is not accounted for as a separate lease (see below for the accounting policy for “lease modifications”).

We present lease liabilities as a separate line item on the consolidated statement of financial position.

Lease modifications

We account for a lease modification as a separate lease if:

- the modification increases the scope of the lease by adding the right to use one or more underlying assets; and
- the consideration for the leases increases by an amount commensurate with the stand-alone price for the increase in scope and any appropriate adjustments to that stand-alone price to reflect the circumstances of the particular contract.

For a lease modification that is not accounted for as a separate lease, we remeasure the lease liability based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

We account for the remeasurement of lease liabilities by making corresponding adjustments to the relevant right-of-use asset. When the modified contract contains a lease component and one or more additional lease or non-lease components, we allocate the consideration in the modified contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

Intangible Assets

Intangible assets acquired separately

Intangible assets with finite useful lives that are acquired separately are carried at costs less accumulated amortization and any accumulated impairment losses. Amortization for intangible assets with finite useful lives is recognized on a straight-line basis over their estimated useful lives. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

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Internally-generated intangible assets — research and development expenditure

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. We recognize development costs as follows:

For class I innovative drugs (innovative drugs that have not been previously approved for marketing in Mainland China), development stage begins after obtaining new drug application approval from drug regulatory organization. Development costs at this stage are recognized as assets when the above six criteria are met.

For generic drugs which have been previously approved for marketing in Mainland China, development stage begins after commencement of bioequivalence tests. Development costs incurred for bioequivalence tests are recognized as assets when the above six criteria are met. Where no internally-generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

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An intangible asset is derecognized on disposal, or when no future economic benefits are expected from use or disposal. Gains and losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognized in profit or loss when the asset is derecognized.

Impairment on Property, Plant and Equipment, Right-of-Use Assets and Intangible Assets

At the end of each Track Record Period, we review the carrying amounts of our property, plant and equipment and right-of-use assets to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any). Intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that may be impaired.

The recoverable amount of property, plant and equipment, right-of-use assets and intangible assets are estimated individually. When it is not possible to estimate the recoverable amount individually, we estimate the recoverable amount of the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing the recoverable amount, the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, we compare the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash-generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognized immediately in profit or loss.

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Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or a cash-generating unit) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

Borrowing Costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, which are assets that necessarily take a substantial period of time to get ready for their intended use or sale, are added to the cost of those assets until such time as the assets are substantially ready for their intended use or sale.

Any specific borrowing that remain outstanding after the related asset is ready for its intended use or sale is included in the general borrowing pool for calculation of capitalisation rate on general borrowings. Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs eligible for capitalisation.

All other borrowing costs are recognised in profit or loss in the period in which there are incurred.

Government Grants

Government grants are not recognized until there is reasonable assurance that we will comply with the conditions attaching to them and that the grants will be received.

Government grants are recognized in profit or loss on a systematic basis over the periods in which we recognize as expenses the related costs for which the grants are intended to compensate. Specifically, government grants whose primary condition is that we should purchase, construct or otherwise acquire non-current assets are recognized as deferred income in the consolidated statement of financial position and transferred to profit or loss on a systematic and rational basis over the useful lives of the related assets.

Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable. Such grants are presented under “other income.”

FINANCIAL INFORMATION

Share-Based Payments

Equity-settled share-based payment transactions

Restricted shares (“RS”) granted to employees

Equity-settled share-based payments to employees are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on our estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payments reserve). At the end of each reporting period, we revise our estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payments reserve.

When shares granted are vested, the amount previously recognized in share-based payments reserve will be transferred to share premium.

Financial Instruments

Financial assets and financial liabilities are recognized when a group entity becomes a party to the contractual provisions of the instrument. All regular way purchases or sales of financial assets are recognized and derecognized on a trade date basis. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the time frame established by regulation or convention in the market place.

Financial assets and financial liabilities are initially measured at fair value except for trade receivable arising from contracts with customers which are initially measured in accordance with IFRS 15. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities (other than financial assets and financial liabilities at fair value through profit or loss (“FVTPL”)) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transaction costs directly attributed to the acquisition of financial assets or financial liabilities at FVTPL are recognized immediately in profit or loss.

The effective interest method is a method of calculating the amortized cost of a financial asset or financial liability and of allocating interest income and interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts and payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial asset or financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

FINANCIAL INFORMATION

Financial assets

Classification and subsequent measurement of financial assets

Financial assets that meet the following conditions are subsequently measured at amortized cost:

- the financial asset is held within a business model whose objective is to collect contractual cash flows; and
- the contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

All other financial assets are subsequently measured at FVTPL.

(i) Amortized cost and interest income

Interest income is recognized using the effective interest method for financial assets measured subsequently at amortized cost and calculated by applying the effective interest rate to the gross carrying amount of a financial asset, except for financial assets that have subsequently become credit-impaired (see below). For financial assets that have subsequently become credit-impaired, interest income is recognized by applying the effective interest rate to the amortized cost of the financial asset from the next reporting period. If the credit risk on the credit-impaired financial instrument improves so that the financial asset is no longer credit-impaired, interest income is recognized by applying the effective interest rate to the gross carrying amount of the financial asset from the beginning of the reporting period following the determination that the asset is no longer credit-impaired.

(ii) Financial assets at FVTPL

Financial assets that do not meet the criteria for being measured at amortized cost are measured at FVTPL.

Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognized in profit or loss. The net gain or loss recognized in profit or loss includes any interest earned on the financial asset and is included in the “other gains and losses, net” line item.

Impairment of financial assets and contract assets subject to impairment assessment under IFRS 9

We perform impairment assessment under expected credit losses (“ECL”) model on financial assets (including trade receivables, other receivables, bank balances and amounts due from subsidiaries) and contract assets which are subject to impairment assessment under IFRS 9. The amount of ECL is updated at each reporting date to reflect changes in credit risk since initial recognition.

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Lifetime ECL represents the ECL that will result from all possible default events over the expected life of the relevant instrument. In contrast, 12-month ECL (“12m ECL”) represents the portion of lifetime ECL that is expected to result from default events that are possible within 12 months after each reporting date. Assessments are done based on our historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current conditions at the reporting date as well as the forecast of future conditions.

We always recognize lifetime ECL for trade receivables and contract assets.

For all other instruments, we measure the loss allowance equal to 12m ECL, unless there has been a significant increase in credit risk since initial recognition, in which case we recognize lifetime ECL. The assessment of whether lifetime ECL should be recognized is based on significant increases in the likelihood or risk of a default occurring since initial recognition.

(i) Significant increase in credit risk

In assessing whether the credit risk has increased significantly since initial recognition, we compare the risk of a default occurring on the financial instrument as at each reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition. In making this assessment, we consider both quantitative and qualitative information that is reasonable and supportable, including historical experience and forward-looking information that is available without undue cost or effort.

In particular, the following information is taken into account when assessing whether credit risk has increased significantly:

- an actual or expected significant deterioration in the financial instrument’s external (if available) or internal credit rating;
- significant deterioration in external market indicators of credit risk, e.g. a significant increase in the credit spread, the credit default swap prices for the debtor;
- existing or forecast adverse changes in business, financial or economic conditions that are expected to cause a significant decrease in the debtor’s ability to meet its debt obligations;
- an actual or expected significant deterioration in the operating results of the debtor;
- an actual or expected significant adverse change in the regulatory, economic, or technological environment of the debtor that results in a significant decrease in the debtor’s ability to meet its debt obligations.

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Irrespective of the outcome of the above assessment, we presume that the credit risk has increased significantly since initial recognition when contractual payments are more than 30 days past due, unless we have reasonable and supportable information that demonstrates otherwise.

We regularly monitor the effectiveness of the criteria used to identify whether there has been a significant increase in credit risk and revises them as appropriate to ensure that the criteria are capable of identifying significant increase in credit risk before the amount becomes past due.

(ii) Definition of default

For internal credit risk management, we consider an event of default occurs when information developed internally or obtained from external sources indicates that the debtor is unlikely to pay its creditors, including us, in full (without taking into account any collaterals held by us).

(iii) Credit-impaired financial assets

A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. Evidence that a financial asset is credit-impaired includes observable data about the following events:

- significant financial difficulty of the issuer or the borrower;
- a breach of contract, such as a default or past due event;
- the lender(s) of the borrower, for economic or contractual reasons relating to the borrower's financial difficulty, having granted to the borrower a concession(s) that the lender(s) would not otherwise consider; or
- it is becoming probable that the borrower will enter bankruptcy or other financial reorganization.

(iv) Write-off policy

We write off a financial asset when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, for example, when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings, whichever occurs sooner. Financial assets written off may still be subject to enforcement activities under our recovery procedures, taking into account legal advice where appropriate. A write-off constitutes a derecognition event. Any subsequent recoveries are recognized in profit or loss.

FINANCIAL INFORMATION

(v) Measurement and recognition of ECL

The measurement of ECL is a function of the probability of default, loss given default (i.e. the magnitude of the loss if there is a default) and the exposure at default. The assessment of the probability of default and loss given default is based on historical data and forward-looking information. Estimation of ECL reflects an unbiased and probability-weighted amount that is determined with the respective risks of default occurring as the weights. Except for those trade receivables of significant balances or with different risk characteristics, we use a practical expedient in estimating ECL on trade receivables collectively and taking into consideration historical credit loss experience and forward looking information that is available without undue cost or effort.

Generally, the ECL is the difference between all contractual cash flows that are due to us in accordance with the contract and the cash flows that we expect to receive, discounted at the effective interest rate determined at initial recognition.

Lifetime ECL for trade receivables and contract assets for CRO services are considered on a collective basis taking into consideration past due information and relevant credit information such as forward-looking macroeconomic information.

For collective assessment, we take into consideration the following characteristics when formulating the grouping:

- Past-due status;
- Nature, size and industry of debtors; and
- External credit ratings where available.

The grouping is regularly reviewed by management to ensure the constituents of each group continue to share similar credit risk characteristics.

Interest income is calculated based on the gross carrying amount of the financial asset unless the financial asset is credit-impaired, in which case interest income is calculated based on amortized cost of the financial asset.

We recognize an impairment gain or loss in profit or loss for all financial instruments by adjusting their carrying amount, with the exception of trade receivables, contract assets, other receivables and amounts due from subsidiaries, where the corresponding adjustment is recognized through a loss allowance account.

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Foreign exchange gains and losses

The carrying amount of financial assets that are denominated in a foreign currency is determined in that foreign currency and translated at the spot rate at the end of each reporting period. Specifically:

For financial assets measured at amortized cost that are not part of a designated hedging relationship, exchange differences are recognized in profit or loss in the “other gains and losses, net” line item as part of the net foreign exchange gains/(losses).

Derecognition of financial assets

We derecognize a financial asset only when the contractual rights to the cash flows from the assets expire.

On derecognition of a financial asset measured at amortized cost, the difference between the asset’s carrying amount and the sum of the consideration received and receivable is recognized in profit or loss.

Financial Liabilities and Equity

Classification as debt or equity

Debt and equity instruments are classified as either financial liabilities or as equity in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by us are recognized at the proceeds received, net of direct issue costs.

Financial liabilities

All financial liabilities are subsequently measured at amortized cost using the effective interest method.

Financial liabilities at amortized cost

Financial liabilities including trade and other payables, amounts due to a related party and borrowings are subsequently measured at amortized cost, using the effective interest method.

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Derecognition of financial liabilities

We derecognize financial liabilities when, and only when, our obligations are discharged, cancelled or have expired. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

Offsetting a financial asset and a financial liability

A financial asset and a financial liability are offset and the net amount presented in the consolidated statement of financial position when, and only when, we currently have a legally enforceable right to set off the recognized amounts; and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

Foreign currencies

In preparing the financial statements of each individual group entity, transactions in currencies other than the functional currency of that entity (foreign currencies) are recognized at the rates of exchanges prevailing on the dates of the transactions. At the end of each Track Record Period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are recognized in profit or loss in the period in which they arise, except for exchange differences on monetary items receivable from or payable to a foreign operation for which settlement is neither planned nor likely to occur (therefore forming part of the net investment in the foreign operation), which are recognized initially in other comprehensive income.

For the purposes of presenting the historical financial information, the assets and liabilities of our operations are translated into the presentation currency of us (i.e. RMB) using exchange rates prevailing at the end of each reporting period. Income and expenses items are translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the date of transactions are used. Exchange differences arising, if any, are recognized in other comprehensive income and accumulated in equity under the heading of translation reserve (attributed to non-controlling interests as appropriate).

Critical Accounting Judgements and Key Sources of Estimation Uncertainty

In the application of our accounting policies, which are described in Note 4, our Directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and underlying assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

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The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Critical Judgements in Applying Accounting Policies

The following are the critical judgements, apart from those involving estimations (see below), that our Directors have made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in the consolidated financial statements.

Research and development expenses

Development expenses incurred on our drug product pipelines are capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete and our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development expenses which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria are met for capitalization.

Key Sources of Estimation Uncertainty

The following are the key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Impairment testing of intangible assets not ready for use

Capitalized development costs and in-licenses are recognized as intangible assets and stated at cost less accumulated amortization and impairment, if any. For the capitalized development costs and in-licenses not yet available for use, we would assess the assets individually for impairment annually. When it is not possible to estimate the recoverable amount of an individual asset, we estimate the recoverable amount of the cash-generating unit to which the assets belongs. In determining whether an asset is impaired, we have to exercise judgment and make estimation, particularly in assessing: (1) whether the carrying value of an asset can be supported by the recoverable amount, which is the higher of the value in use, or fair value less costs of disposal; and (2) the appropriate key assumptions to be applied in estimating the recoverable amounts including cash flow projections and an appropriate discount rate. Changing the assumptions and estimates as set out in Note 19 of the Accountants' Report set forth in Appendix IA to this document in the cash flow projections, could materially affect the net present value used in the impairment test.

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OUR CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Revenue	199,651	194,387	9,996
Cost of sales	(6,014)	(5,399)	(6,210)
Gross profit	193,637	188,988	3,786
Other income	5,974	2,284	7,271
Other gains and losses, net	222	(4)	176
Research and development expenses	(131,297)	(102,007)	(100,481)
Administrative expenses	(51,187)	(39,425)	(50,936)
Selling expenses	(1,322)	(776)	(2,933)
Impairment losses under ECL model, net of reversal	(2,400)	(2,673)	(1,269)
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Finance costs	(7,200)	(4,016)	(11,986)
Profit/(loss) before tax	6,427	42,371	(156,372)
Income tax expense	–	–	–
Profit/(loss) for the year/period	6,427	42,371	(156,372)
Exchange differences arising on translation of foreign operations	(285)	(209)	(240)
Total comprehensive income/(expense) for the year/period	6,142	42,162	(156,612)
Profit/(loss) for the year/period attributable to:			
Owners of the Company	12,089	48,510	(150,866)
Non-controlling interests	(5,662)	(6,139)	(5,506)
	<u>6,427</u>	<u>42,371</u>	<u>(156,372)</u>

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DESCRIPTION OF MAJOR COMPONENTS OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Revenue

During the Track Record Period, we generated revenue from (i) payments from milestones and assignment of rights and royalty payments in relation to VV116; (ii) provision of CRO services to certain pharmaceutical companies in the PRC; and (iii) sales of pharmaceutical products. The following table sets forth a breakdown of our revenue for the year/periods indicated:

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Out-licensing income			
– Payments from milestones and assignment of rights	184,340	179,811	–
– Royalty payments	11,817	11,684	5,382
Subtotal	196,157	191,495	5,382
CRO services	2,820	2,218	4,032
Sales of pharmaceutical products⁽¹⁾	674	674	582
Total	<u>199,651</u>	<u>194,387</u>	<u>9,996</u>

Note:

- (1) Revenue generated from sales of pharmaceutical products comprises revenue generated from (i) the sales of our generic drug, dapoxetine in the PRC and (ii) the sales of pharmaceutical products in Uzbekistan. We only recorded revenue generated from sales of dapoxetine in the PRC of RMB0.6 million in the nine months ended September 30, 2024. In 2023, and the nine months ended September 30, 2023 and 2024, revenue generated from our sales of pharmaceutical products in Uzbekistan amounted to RMB0.7 million, RMB0.7 million and RMB12.0 thousand, respectively.

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Cost of Sales

During the Track Record Period, our cost of sales consisted of (i) royalties paid by us in relation to the sales of VV116. For details, see “Business — Collaboration Arrangement — VV116 Agreements”; (ii) staff costs; (iii) material costs; (iv) depreciation and amortization; and (v) other miscellaneous costs. The following table sets forth a breakdown of our cost of sales for the year/periods indicated:

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Royalties	3,758	3,715	1,711
Staff costs	1,303	835	1,287
Material costs	775	717	306
Depreciation and amortization	86	65	2,632
Others	92	67	274
	<u>6,014</u>	<u>5,399</u>	<u>6,210</u>

Gross Profit and Gross Profit Margin

During the Track Record Period, our gross profit represents our revenue less our cost of sales. Our gross profit margin represents our gross profit as a percentage of our revenue. Our gross profit amounted to RMB193.6 million in 2023, and our gross profit margin for the year was 97.0%. In the nine months ended September 30, 2023 and 2024, we recorded gross profit of RMB189.0 million and RMB3.8 million, respectively, and our gross profit margin for each period was 97.2% and 37.9%, respectively.

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Other Income

During the Track Record Period, other income primarily consisted of (i) government grants, mainly representing subsidies granted by the PRC government authorities to us as incentives for our research and development activities and talent development. The government grants included unconditional and conditional subsidies which had been approved by the PRC government authorities. The unconditional government grants are recognized when payments were received. The conditional government grants are recognized when condition are met and the corresponding grants are received and (ii) bank interest income, primarily representing interest income on our bank deposits. The following table sets forth a breakdown of our other income for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Government grants	3,988	1,138	6,682
Bank interest income	1,792	985	562
Others	194	161	27
Total	<u>5,974</u>	<u>2,284</u>	<u>7,271</u>

Other Gains and Losses, Net

During the Track Record Period, net other gains and losses primarily included (i) net foreign exchanges gains, mainly representing the gains from the fluctuations in exchange rates between USD and RMB; (ii) gains arising on financial assets measured at FVTPL, mainly representing gains on low-risk and principal-guaranteed wealth management products purchased by us from commercial banks in the PRC; and (iii) losses on lease modification. The following table sets forth a breakdown of our net other gains and losses for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Net foreign exchange gains	246	16	213
Gains arising from financial assets at FVTPL	–	–	179
Losses on lease modification	–	–	(154)
Others	(24)	(20)	(62)
Total	<u>222</u>	<u>(4)</u>	<u>176</u>

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Research and Development Expenses

During the Track Record Period, our research and development expenses consisted of (i) trial and testing expenses for our drug candidates; (ii) employee benefit expenses relating to salaries, bonus and other welfare for our research and development personnel; (iii) depreciation and amortization expenses in relation to our property, plant and equipment as well as intangible assets which were used for research and development purpose; (iv) utilities and office expenses incurred for our research and development activities; (v) material costs incurred in the course of our R&D activities; and (vi) others, mainly comprising traveling expenses of our research and development personnel, and other miscellaneous expenses. In addition to research and development expenses recorded in our statements of profit or loss, we also capitalized a portion of our investment in research and development. For details of our capitalized development spending, see “— Discussion of Certain Selected Items from The Consolidated Statements of Financial Position — Intangible Assets.” The following table sets forth a breakdown of our research and development expenses by nature for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Trial and testing expenses	57,538	48,774	47,887
Employee benefit expenses	44,393	32,496	30,814
Depreciation and amortization	10,273	6,216	7,309
Utilities and office expenses	6,478	5,958	7,019
Material costs	10,707	7,043	5,541
Others	1,908	1,520	1,911
Total	<u>131,297</u>	<u>102,007</u>	<u>100,481</u>

The following table sets forth our research and development expenses attributable to the Core Products during the Track Record Period by development stage.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
VV116			
– Phase I	9,384	8,697	4,391
– Phase II	210	–	7,028
	<u>9,594</u>	<u>8,697</u>	<u>11,419</u>

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	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
TPN171			
– Phase I	2,697	2,697	–
– Phase II	3,023	3,023	–
– Phase III	<u>28,647</u>	<u>21,981</u>	<u>24,154</u>
	34,367	27,701	24,154
LV232			
– Phase I	<u>6,295</u>	<u>4,263</u>	<u>6,809</u>
Total	<u>50,256</u>	<u>40,661</u>	<u>42,382</u>

Administrative Expenses

During the Track Record Period, our administrative expenses consisted of (i) employee benefits expenses mainly relating to salaries, bonus and other welfare for our administrative personnel; (ii) share-based compensation expenses, in connection with the restricted shares granted to our key management; (iii) depreciation and amortization related to assets for office and general purposes; (iv) professional service fees paid to legal advisors, auditors, and other consultants; (v) utilities and office expenses incurred for our administrative purpose; and (vi) others, mainly including tax and surcharges, travelling expenses and other miscellaneous expenses. The following table sets forth a breakdown of our administrative expenses for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Employee benefit expense	18,855	13,497	21,491
Share-based compensation expenses	14,745	11,062	11,062
Depreciation and amortization	5,772	4,820	9,238
Professional service fees	3,784	3,429	2,855
Utilities and office expenses	6,760	5,604	5,078
Others	<u>1,271</u>	<u>1,013</u>	<u>1,212</u>
Total	<u>51,187</u>	<u>39,425</u>	<u>50,936</u>

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Selling Expenses

During the Track Record Period, our selling expenses consisted of (i) employee benefits expenses, mainly relating to salaries, bonus and other welfare for our in-house selling and marketing personnel; (ii) marketing, promotion and advertising expenses; (iii) office expenses incurred for our selling and marketing activities; and (iv) others, mainly including depreciation and amortization expenses and other miscellaneous expenses. The following table sets forth a breakdown of our selling expenses for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Employee benefit expenses	1,062	718	1,687
Marketing, promotion and advertising expenses	183	42	791
Office expenses	15	12	415
Others	62	4	40
Total	<u>1,322</u>	<u>776</u>	<u>2,933</u>

Impairment Losses Under ECL Model, Net of Reversal

During the Track Record Period, our impairment losses under ECL model, net of reversal primarily represented the allowances for ECLs on trade receivables, other receivables and contract assets. For details of impairment assessment, see Note 39(b) of the Accountants’ Report set forth in Appendix IA to this document. The following table sets forth a breakdown of our impairment losses under ECL model, net of reversal for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Impairment losses recognized/(reversed) on			
– trade receivables	1,683	2,435	1,914
– other receivables	(183)	141	(101)
– contract assets	900	97	(544)
Total	<u>2,400</u>	<u>2,673</u>	<u>1,269</u>

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Finance Costs

During the Track Record Period, our finance costs consisted of (i) interest on borrowings, mainly representing the interests incurred on bank loans we obtained to fund our capital expenditures and working capital. We capitalize interest expenses on bank loans incurred for the construction of our manufacturing facility in Lianyungang and a new R&D center in Suzhou; (ii) interest on lease liabilities; (iii) interest on financial liabilities at amortized cost in relation to the redemption rights granted by us to one of the Series C Investors. For details, see “— Discussion of Certain Selected Items From The Consolidated Statements of Financial Position — Financial Liabilities at Amortized Cost” and Note 23 of the unaudited financial information for the nine months ended September 30, 2024 to the Accountants’ Report in Appendix IB to this document; and (iv) interest on loan from a related party, mainly relating to our loan from Topharman Shanghai. For more details, see “— Related Party Transactions.” The following table sets forth a breakdown of our finance costs for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Interest on borrowings	10,796	6,609	9,471
<i>Less: amounts capitalized in the cost of construction in progress</i>	<u><i>(5,386)</i></u>	<u><i>(3,917)</i></u>	<u><i>(348)</i></u>
	5,410	2,692	9,123
Interest on lease liabilities	1,405	1,035	1,329
Interest on financial liabilities at amortized cost	—	—	1,245
Interest on loan from a related party	<u>385</u>	<u>289</u>	<u>289</u>
	<u>7,200</u>	<u>4,016</u>	<u>11,986</u>

Income Tax Expense

Income tax expense represents the sum of current and deferred income tax expense. Our Directors confirm that during the Track Record Period, we had made all the required tax filings and had paid all outstanding tax liabilities with the relevant tax authorities in the relevant jurisdictions and we are not aware of any outstanding or potential disputes with such tax authorities.

Under the Law of the PRC on Enterprise Income Tax, or the EIT Law, and Implementation Regulation of the EIT Law, the EIT rate of our PRC subsidiaries was 25% during the Track Record Period. Our Company was accredited as a “High and New Technology Enterprise” in 2022 and may be entitled to a preferential tax rate of 15% for a term of three years commencing from the year of accreditation, subject to certain conditions. In addition, Pursuant to Caishui 2023 circular No. 7, our Company enjoyed super deduction of 200% on qualified research and development expenditures in 2023. Vigonvita Tashkent was subject to the Uzbekistan Corporate Income Tax rate of 15% in 2023.

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No provision for taxation in the PRC or Uzbekistan has been made as we have no taxable profit in 2023 and the nine months ended September 2023 and 2024, respectively. For details, see Note 12 of the Accountants’ Report set forth in Appendix IA and Note 9 of the unaudited financial information for the nine months ended September 30, 2024 set forth in Appendix IB to this document.

PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

Nine Months Ended September 30, 2024 Compared With Nine Months Ended September 30, 2023

Revenue

Our revenue decreased significantly from RMB194.4 million for the nine months ended September 30, 2023 to RMB10.0 million for the nine months ended September 30, 2024, primarily due to a significant decrease in out-licensing income of RMB186.1 million, as (i) certain research and development milestones of VV116 which would trigger the milestone payment obligations had been reached in 2023, and (ii) the payments in connection with assignment of exclusive rights as the API provider for VV116 had been recorded in 2023. In comparison, we did not recognize any payments from milestones and assignment of rights in the nine months ended September 30, 2024. The decrease was partially offset by an increase in revenue generated from our provision of CRO services of RMB1.8 million. The amount of revenue generated from our provision of CRO services as recognized in our profit or loss is associated with the milestones of relevant research activities that have been reached, and therefore will fluctuate from period to period based on the progress of the research activities.

Cost of Sales

Our cost of sales increased from RMB5.4 million for the nine months ended September 30, 2023 to RMB6.2 million for the nine months ended September 30, 2024, primarily due to an increase in depreciation and amortization of RMB2.6 million, partially offset by a decrease in royalties paid by us of RMB2.0 million, which was in line with the decreased royalty payments in relation to VV116 that we received.

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Gross Profit and Gross Profit Margin

As a result of foregoing, our gross profit decreased from RMB189.0 million in the nine months ended September 30, 2023 to RMB3.8 million in the nine months ended September 30, 2024. Our gross profit margin decreased from 97.2% in the nine months ended September 30, 2023 to 37.9% in the nine months ended September 30, 2024, primarily because payments from milestones and assignment of rights contributed a significant portion of our revenue in the nine months ended September 30, 2023, for which we did not record any cost of sales.

Other Income

Our other income increased from RMB2.3 million for the nine months ended September 30, 2023 to RMB7.3 million for the nine months ended September 30, 2024, primarily due to an increase in government grants of RMB5.5 million from PRC government authorities as incentives for our research and development activities and talent development.

Other Gains and Losses, Net

We had net other gains of RMB176.0 thousand for the nine months ended September 30, 2024, compared to net other losses of RMB4.0 thousand that we recorded for the nine months ended September 30, 2023, primarily due to (i) an increase in net foreign exchange gains of RMB197.0 thousand, resulting from the fluctuations in exchange rates between USD and RMB; and (ii) an increase in gains from low-risk and principal-guaranteed wealth management products of RMB179.0 thousand, partially offset by the losses on lease modification of RMB154.0 thousand we recorded one-off in the nine months ended September 30, 2024.

Research and Development Expenses

Our research and development expenses remained relatively stable at RMB102.0 million for the nine months ended September 30, 2023 and RMB100.5 million for nine months ended September 30, 2024, respectively.

Administrative Expenses

Our administrative expenses increased from RMB39.4 million for the nine months ended September 30, 2023 to RMB50.9 million for the nine months ended September 30, 2024, primarily due to (i) an increase in employee benefit expenses of RMB7.9 million due to the increased headcount of administrative team to support our operations; and (ii) an increase in depreciation and amortization of RMB4.4 million.

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Selling Expenses

Our selling expenses increased from RMB0.8 million for the nine months ended September 30, 2023 to RMB2.9 million for the nine months ended September 30, 2024, primarily due to (i) an increase in employee benefit expenses of RMB1.0 million as a result of the increased headcount of selling and marketing team and (ii) an increase in marketing, promotion and advertising expenses of RMB0.7 million, to support our increased sales and marketing efforts for the commercialization of our drugs in commercial and near-commercial stage.

Impairment Losses Under ECL Model, Net of Reversal

Our impairment losses under ECL model, net of reversal decreased from RMB2.7 million for the nine months ended September 30, 2023 to RMB1.3 million for the nine months ended September 30, 2024, mainly due to (i) a change of RMB0.6 million, arising from the reversal of RMB0.5 million in impairment losses on contract assets in the nine months ended September 30, 2024, compared to the impairment losses on contract assets in the same period of 2023 and (ii) a decrease in impairment losses on trade receivables of RMB0.5 million, mainly because we individually assessed the credit risk and recognized impairment losses for two customers in the nine months ended September 30, 2023.

Finance Costs

Our finance costs increased from RMB4.0 million for the nine months ended September 30, 2023 to RMB12.0 million for the nine months ended September 30, 2024, primarily due to (i) an increase in interest on borrowings (less amounts capitalized in the cost of construction in progress) of RMB6.4 million, mainly attributable to an increase in borrowings to support our operations; and (ii) an increase in interest on financial liabilities at amortized cost of RMB1.2 million, as we granted redemption rights to one of the Series C investors in April 2024.

Profit/Loss for the Period

As a result of the foregoing, we recorded profit for the period of RMB42.4 million for the nine months ended September 30, 2023, and loss for the period of RMB156.4 million for the nine months ended September 30, 2024.

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DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
ASSETS		
Non-current assets		
Property, plant and equipment	309,082	325,601
Right-of-use assets	126,277	128,499
Intangible asset	68,074	76,735
Other non-current assets	6,679	31,299
Total non-current assets	510,112	562,134
Current assets		
Inventories	3,209	4,345
Trade receivables	36,552	12,550
Prepayments and other receivables	6,639	6,977
Contract assets	2,414	833
Other current assets	21,396	34,973
Bank balances and cash	95,974	95,052
Total current assets	166,184	154,730
LIABILITIES		
Current liabilities		
Trade and other payables	123,176	108,435
Contract liabilities	6,961	4,748
Amounts due to a related party	10,882	11,171
Lease liabilities	10,860	11,499
Financial liabilities at amortized cost	–	51,245
Borrowings	133,751	167,749
Deferred income	179	12,945
Total current liabilities	285,809	367,792
Net current liabilities	(119,625)	(213,062)
Total assets less current liabilities	390,487	349,072

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	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Non-current liabilities		
Lease liabilities	30,642	32,842
Borrowings	145,775	199,610
Deferred income	25,954	13,054
Total non-current liabilities	202,371	245,506
Net assets	188,116	103,566
Capital and reserves		
Share capital	6,361	6,526
Reserves	192,733	112,524
Equity attributable to owners of the Company	199,094	119,050
Non-controlling interests	(10,978)	(15,484)
Total equity	188,116	103,566

Property, Plant and Equipment

Our property, plant and equipment primarily includes machinery and equipment, office equipment and fixtures, leasehold improvement, buildings, vehicles and construction in progress. Our property, plant and equipment increased from RMB309.1 million as of December 31, 2023 to RMB325.6 million as of September 30, 2024, primarily due to (i) an increase in buildings, as our manufacturing facility in Lianyungang commenced operations in June 2024, and therefore we derecognized the relevant amount in construction in progress and recognized to buildings; and (ii) an increase in machinery and equipment as we purchased additional equipment to support our business expansion, partially offset by a decrease in construction in progress due to the reason as abovementioned. The following table sets out our property, plant and equipment as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Machinery and equipment	40,070	45,868
Office equipment and fixtures	2,050	1,077
Leasehold improvements	11,397	9,866
Buildings	48	227,561
Vehicles	66	52
Construction in progress	255,451	41,177
Total	309,082	325,601

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Right-of-Use Assets

Our right-of-use assets primarily arise from the leased properties and land use rights. Our right-of-use assets remained relatively stable at RMB126.3 million as of December 31, 2023 and RMB128.5 million as of September 30, 2024. The following table sets out our right-of-use assets as of the dates indicated.

	As of December 31, 2023	As of September 30, 2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Leased properties	40,542	44,693
Land use rights	85,735	83,806
Total	126,277	128,499

Intangible Assets

Our intangible assets consist of (i) in-licenses for our drug candidates; (ii) capitalized development costs in relation to three generic drugs, namely dapoxetine, rebamipide and brexpiprazole; (iii) software; and (iv) intellectual properties. For details of the in-licenses, see Note 18 of the Accountants’ Report set forth in Appendix IA to this document. Our intangible assets increased from RMB68.1 million as of December 31, 2023 to RMB76.7 million as of September 30, 2024, primarily because we reclassified the capitalized development costs for dapoxetine to intellectual properties. The following table sets out our intangible asset as of the dates indicated.

	As of December 31, 2023	As of September 30, 2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
In-licenses	51,280	53,440
Capitalized development costs	16,408	9,441
Software	386	384
Intellectual properties	–	13,470
Total	68,074	76,735

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Other Non-current Assets

Our other non-current assets consist of (i) prepayments for property, plant and equipment representing our prepaid construction payments for our new R&D center in Suzhou; (ii) long-term deposits and (iii) VAT recoverable. Our other non-current assets increased from RMB6.7 million as of December 31, 2023 to RMB31.3 million as of September 30, 2024, mainly due to the increase in prepaid construction payments for our new R&D center in Suzhou, which we expect will gradually decrease and be reclassified to construction in progress according to the construction progress in the future. The following table sets out our other non-current assets as of the dates indicated.

	As of December 31, 2023	As of September 30, 2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Prepayments for property, plant and equipment	492	29,347
Long-term deposits	1,738	1,952
VAT recoverable	4,449	–
Total	6,679	31,299

Inventories

Our inventories primarily consist of (i) raw materials and consumables to be used mainly for our manufacturing and research and development activities; (ii) work in progress, reflecting the amount of pharmaceutical products that are under production and (iii) finished goods, reflecting the stock level of our pharmaceutical products available for sale. Our inventories increased from RMB3.2 million as of December 31, 2023 to RMB4.3 million as of September 30, 2024, mainly due to the increase in our finished goods, as we started to sell dapoxetine in 2024. The following table sets forth the details of our inventories as of the dates indicated.

	As of December 31, 2023	As of September 30, 2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Raw materials and consumables	3,174	3,411
Work in progress	–	175
Finished goods	35	759
Total	3,209	4,345

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The following table sets forth the aging analysis of our inventories as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Up to 30 days	198	955
31-90 days	62	47
91-180 days	571	616
181-365 days	2,378	2,727
Total	3,209	4,345

As of November 30, 2024, RMB2.0 million of inventories, accounting for 46.1% of inventories as of September 30, 2024, had been subsequently utilized.

Trade Receivables

Our trade receivables primarily represent the balances due from our customers in relation to the out-licensing of VV116, our provision of CRO services and the sales of pharmaceutical products. Our trade receivables decreased significantly from RMB36.6 million as of December 31, 2023 to RMB12.6 million as of September 30, 2024, primarily because we received certain payments from milestones and assignment of rights in relation to VV116 during the first half of 2024. The following table sets forth the details of our trade receivables as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Trade receivables	38,773	14,285
<i>Less: allowance for credit losses</i>	<i>(2,221)</i>	<i>(1,735)</i>
Total	36,552	12,550

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We typically grant credit terms of 30 to 60 days to customers. We seek to maintain strict credit control over our outstanding receivables, and overdue balances are reviewed regularly and actively monitored by senior management to minimize credit risk. The following table sets forth an aging analysis of our trade receivables net of allowance for credit losses, based on the invoice date.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
1 to 30 days	16,174	12,002
31-60 days	20,000	–
61-90 days	–	4
91-120 days	–	157
121 to 180 days	45	19
181 to 360 days	–	–
Over 360 days	333	368
Total	36,552	12,550

As of November 30, 2024, RMB4.1 million, or approximately 32.4% of our trade receivables as of September 30, 2024 had been subsequently settled.

Prepayments and Other Receivables

Our prepayments and other receivables mainly consist of (i) prepayments for purchase of materials and research and development services, representing prepayments to service providers for our preclinical and clinical research and development; (ii) other receivables; (iii) deposits; and (iv) prepayments for short-term rental and property management fee. Our prepayment and other receivables remained relatively stable at RMB6.6 million as of December 31, 2023 and RMB7.0 million as of September 30, 2024. The following table sets out our prepayment and other receivables as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Prepayments for purchase of materials and research and development services	4,117	5,684
Other receivables	2,263	345
<i>Less: allowance for credit losses</i>	<i>(113)</i>	<i>(12)</i>
Deposits	242	578
Prepayments for short-term rental and property management fee	130	177
Others	–	205
Total	6,639	6,977

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Bank Balances and Cash

Our bank balances and cash primarily consist of cash at hand as well as bank balances, which carry interest rates ranging from 0.25% to 2.00% as of December 31, 2023, and 0.20% to 1.20% as of September 30, 2024, respectively. Our bank balances and cash remained relatively stable at RMB96.0 million and RMB95.1 million as of December 31, 2023 and September 30, 2024, respectively. For an analysis on cash flows during the Track Record Period, see “— Liquidity and Capital Resources.”

Trade and Other Payables

Our trade and other payables primarily consist of (i) trade payables for research and development expenses; (ii) accrued research and development expenses; (iii) payables for construction in progress; (iv) accrued staff costs and benefits; (v) payables in respect of acquisition of intangible assets; (vi) payables for machinery and equipment; (vii) other tax payables; and (viii) deposits. Our trade and other payables decreased from RMB123.2 million as of December 31, 2023 to RMB108.4 million as of September 30, 2024, mainly due to the decreases in payables for construction in progress and payables for machinery and equipment, as we gradually settled the outstanding balances according to our acceptance progress of the manufacturing facility in Lianyungang. The following table sets out our trade and other payables as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Trade payables for research and development expenses	615	1,083
Accrued research and development expenses	19,710	19,576
Payables for construction in progress	85,884	74,982
Accrued staff costs and benefits	9,549	8,148
Payables in respect of acquisition of intangible assets	2,750	2,750
Payables for machinery and equipment	2,406	923
Other tax payables	1,590	629
Deposits	672	344
Total	123,176	108,435

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The following table sets forth an aging analysis of our trade payables based on the invoice dates as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
0 – 30 days	256	626
31 – 90 days	16	28
91 – 180 days	46	235
181 – 365 days	153	14
Over 365 days	144	180
Total	615	1,083

Our Directors confirmed that there had been no material defaults in payment of trade and other payables during the Track Record Period and up to the Latest Practicable Date.

As of November 30, 2024, RMB0.3 million, or 28.8%, of our trade payables as of September 30, 2024 had been subsequently settled.

Financial Liabilities at Amortized Cost

Our financial liabilities at amortized cost primarily represent the redemption liabilities of ordinary shares that we issued to one of the Series C Investors in April 2024. For details, see Note 23 of the unaudited financial information for the nine months ended September 30, 2024 set forth in Appendix IB to this document. In April 2024, we received an investment of RMB50.0 million from such Series C Investor and recognized our obligation to return the investment and the relevant interest to this investor with redemption rights as financial liabilities at amortized cost. As of December 31, 2023 and September 30, 2024, our financial liabilities at amortized cost amounted to nil and RMB51.2 million, respectively.

In accordance with Pre-[REDACTED] Investment Guidance in Chapter 4.2 of the Guide, all these special rights have been terminated prior to the first filing of the [REDACTED] by our Company with the Stock Exchange, except for certain conditions. For details, see “History, Development and Corporate Structure — Pre-[REDACTED] Investments — Rights of the Pre-[REDACTED] Investors.” The amounts of the financial liabilities at amortized cost were derecognized and credited to other reserve as of the Latest Practicable Date.

FINANCIAL INFORMATION

LIQUIDITY AND CAPITAL RESOURCES

Overview

During the Track Record Period, we primarily funded our operations through a combination of equity and debt financing, supplemented by cash generated from operations. We expect that our cash needs in the near future will primarily relate to our marketing and promotion of our commercialized products, progressing the development of our drug candidates towards receiving regulatory approval and commencing commercialization, as well as expanding our drug candidate portfolio. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Going forward, we expect our liquidity requirements will be satisfied by a combination of revenue generated from the sales of our commercialized products and out-licensing arrangements, existing cash and cash equivalents, bank loans, and net [REDACTED] from the [REDACTED]. With the continuing growth of our business and expansion of our pipeline, additional funding may be required through public or private [REDACTED], debt financing, or other sources.

Cash Flows

The following table sets forth our consolidated statements of cash flows for the year/periods indicated.

	<u>Year Ended December 31,</u>	<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2023</u>	<u>2024</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Cash generated from/(used in) operations before movements in working capital	47,366	72,343	(107,699)
Changes in working capital	<u>(16,697)</u>	<u>(28,178)</u>	<u>(3,203)</u>
Net cash flows generated from/(used in) operating activities	30,669	44,165	(104,466)
Net cash flows used in investing activities	(160,871)	(125,112)	(74,586)
Net cash flows generated from financing activities	<u>76,501</u>	<u>59,754</u>	<u>177,917</u>
Net decrease in cash and cash equivalents	(53,701)	(21,193)	(1,135)
Cash and cash equivalents at beginning of the year/period	149,429	149,429	95,974
Effect of foreign exchange rate changes	<u>246</u>	<u>16</u>	<u>213</u>
Cash and cash equivalents at end of the year/period	<u>95,974</u>	<u>128,252</u>	<u>95,052</u>

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Net Cash Flows Generated From/Used in Operating Activities

For the nine months ended September 30, 2024, we used RMB104.5 million in cash in operating activities. The difference with RMB156.4 million of loss before income tax was mainly the result of adding back non-cash items such as (i) RMB15.1 million of depreciation of property, plant and equipment, (ii) RMB12.0 million of finance costs, (iii) RMB11.1 million of share-based payment expense, and (iv) RMB9.1 million of depreciation of right-of-use assets. In addition, a total of RMB3.2 million of cash was used in our working capital as (i) our other current assets increased by RMB13.6 million, (ii) our trade and other payables decreased by RMB8.2 million, and (iii) our contract liabilities decreased by RMB2.2 million, partially offset by a decrease of trade receivables of RMB21.9 million.

In 2023, we generated RMB30.7 million in cash from operating activities. The difference with RMB6.4 million of profit before income tax was mainly the result of adding back non-cash items such as (i) RMB14.7 million of share-based payment expenses, (ii) RMB10.0 million of depreciation of right-of-use assets, (iii) RMB7.2 million of finance costs, and (iv) RMB6.9 million of depreciation of property, plant and equipment. In addition, a total of RMB16.7 million of cash was used in our working capital as (i) our trade receivables, prepayments and other receivables increased by RMB26.0 million, (ii) our other current assets increased by RMB4.8 million, and (iii) our other non-current assets increased by RMB3.9 million, partially offset by (i) an increase in trade and other payables of RMB16.7 million, and (ii) an increase in deferred income of RMB7.7 million.

Net Cash Flows Used in Investing Activities

For the nine months ended September 30, 2024, we used RMB74.6 million in cash in investing activities, primarily as a result of (i) purchase of financial assets at FVTPL of RMB100.0 million, and (ii) purchase of property, plant and equipment of RMB65.8 million, partially offset by proceeds on disposal of financial assets at FVTPL of RMB100.2 million.

In 2023, we used RMB160.9 million in cash in investing activities, primarily as a result of (i) purchase of property, plant and equipment of RMB86.7 million, (ii) payments for right-of-use assets of RMB46.4 million, and (iii) purchase of intangible asset of RMB26.1 million.

Net Cash Flows Generated From Financing Activities

For the nine months ended September 30, 2024, we generated RMB177.9 million in cash from financing activities, primarily as a result of (i) proceeds from borrowings of RMB188.1 million, and (ii) proceeds from issue of Series C shares of RMB110.0 million, partially offset by repayments of borrowings of RMB100.2 million.

In 2023, we generated RMB76.5 million from financing activities, primarily as a result of proceeds from borrowings of RMB172.3 million, partially offset by (i) repayments of borrowings of RMB75.1 million, (ii) interest paid of RMB11.8 million, and (iii) repayments of lease liabilities of RMB8.9 million.

FINANCIAL INFORMATION

Net Current Liabilities

	As of December 31, <u>2023</u> <i>RMB'000</i>	As of September 30, <u>2024</u> <i>RMB'000</i> <i>(unaudited)</i>	As of November 30, <u>2024</u> <i>RMB'000</i> <i>(unaudited)</i>
Current assets			
Inventories	3,209	4,345	6,160
Trade receivables	36,552	12,550	10,791
Prepayments and other receivables	6,639	6,977	4,514
Contract assets	2,414	833	176
Other current assets	21,396	34,973	15,127
Bank balances and cash	95,974	95,052	61,383
Total current assets	<u>166,184</u>	<u>154,730</u>	<u>98,151</u>
Current liabilities			
Trade and other payables	123,176	108,435	110,535
Contract liabilities	6,961	4,748	4,565
Amounts due to a related party	10,882	11,171	11,235
Lease liabilities	10,860	11,499	13,005
Financial liabilities at amortized cost	–	51,245	51,703
Borrowings	133,751	167,749	120,906
Deferred income	179	12,945	12,900
Total current liabilities	<u>285,809</u>	<u>367,792</u>	<u>324,849</u>
Net current liabilities	<u>(119,625)</u>	<u>(213,062)</u>	<u>(226,698)</u>

Our net current liabilities increased from RMB119.6 million as of December 31, 2023 to RMB213.1 million as of September 30, 2024, primarily due to (i) an increase in financial liabilities at amortized cost mainly due to the redemption right granted by us to one of Series C Investors; (ii) an increase in borrowings to support our operations; and (iii) a decrease in trade receivables, mainly because we received certain payments from milestones and assignment of rights in relation to VV116 during the first half of 2024, partially offset by a decrease in trade and other payables, mainly due to our settlement of the outstanding balances according to our acceptance progress of the manufacturing facility in Lianyungang.

Our net current liabilities increased to RMB226.7 million as of November 30, 2024, primarily due to (i) a decrease in bank balances and cash, mainly due to our repayment of bank borrowings and cash outflows in operating activities, and (ii) a decrease in other current assets, mainly due to the decrease in VAT recoverable, partially offset by a decrease in current portion of borrowings, mainly due to our repayment of bank borrowings.

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Working Capital Confirmation

We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. In view of our net operating cash outflows in the nine months ended September 30, 2024, we plan to improve such position by (i) continuously advancing our pipeline products towards commercialization to generate revenue from product sales. In particular, we expect to generate revenue from the future sales of TPN171 once approved for commercialization in China as we expect to obtain NDA approval from the NMPA around mid-2025. In addition, we expect to continue to generate revenue from the royalty payments in relation to VV116; (ii) adopting comprehensive measures to effectively control our costs and operating expenses and enhancing working capital management efficiency. For example, we plan to conduct periodic reviews of our financial performance and utilize technological solutions to optimize our operational processes and enhance our efficiency; and (iii) successfully launching the [REDACTED] to obtain net [REDACTED]. As of November 30, 2024, we had unutilized banking facilities of RMB336.0 million.

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED], as well as cash burn rate, we have available sufficient working capital to cover at least 125% of the Group’s costs, including general, administrative and operating costs (including any production costs), research and development costs, and repayments to amounts due to a related party, for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly amount of (i) net cash used in operating activities, and (ii) capital expenditures. Assuming an average cash burn rate going forward of 2.1 times the level in 2023, taking into account that we have received net proceeds of RMB50.0 million from our Series C Financing in the fourth quarter of 2024, and the estimated net [REDACTED] (based on the [REDACTED] of [REDACTED] per Share, being the [REDACTED] of the indicative [REDACTED] stated in this document), we estimate that our cash and cash equivalents as of September 30, 2024 will be able to maintain our financial viability for 35 months from September 30, 2024. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing at least six months after the completion of the [REDACTED].

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CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Research and development costs			
<i>Research and development costs for</i>			
<i>Core Products</i>			
– trial and testing expenses	31,165	25,222	33,782
– staff costs	7,308	5,460	6,288
– raw materials and others	2,890	640	1,508
<i>Research and development costs for</i>			
<i>other product candidates</i>			
– trial and testing expenses	15,427	11,031	12,992
– staff costs	35,800	26,048	31,393
– raw materials and others	5,996	2,676	4,554
Workforce employment costs	22,075	14,639	22,009
Direct production costs	662	630	626
Product marketing	258	54	1,664
Total	121,581	86,400	114,816

FINANCIAL INFORMATION

INDEBTEDNESS

Our indebtedness during the Track Record Period included lease liabilities, borrowings, financial liabilities at amortized cost and amounts due to a related party. Except as disclosed in the table below, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of November 30, 2024. After due and careful consideration, our Directors confirm that there had been no material adverse change in our indebtedness since November 30, 2024 and up to the Latest Practicable Date. The following table sets forth a breakdown of our indebtedness as of the dates indicated.

	As of December 31,	As of September 30,	As of November 30,
	2023	2024	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Lease liabilities	41,502	44,341	41,694
Borrowings	279,526	367,359	350,219
Financial liabilities at amortized cost ⁽¹⁾	–	51,245	51,703
Amounts due to a related party ⁽¹⁾	10,882	11,171	11,235
Total	331,910	474,116	454,851

Note:

- (1) Financial liabilities at amortized cost and amounts due to a related party were unsecured and unguaranteed.

Lease Liabilities

Our lease liabilities are in relation to properties that we leased for our business operations. We recognized lease liabilities in respect of all of our operating leases, except for short-term leases and leases of low-value assets.

Our lease liabilities increased from RMB41.5 million as of December 31, 2023 to RMB44.3 million as of September 30, 2024, mainly due to the new lease entered into in May 2024. Our lease liabilities decreased to RMB41.7 million as of November 30, 2024, mainly due to the lease payments we made.

As of November 30, 2024, lease liabilities of RMB29.9 million was secured by rental deposits and unguaranteed. The remaining portion of lease liabilities amounting to RMB11.8 million were unsecured and unguaranteed.

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Borrowings

Our borrowings consist of bank loans and other loans in respect of sale and leaseback arrangement to finance our manufacturing and research and development activities. During the Track Record Period, the interest rates of our borrowings ranged from 2.8% to 5.50% per annum. The following table sets forth a breakdown of our borrowings as of the dates indicated.

	As of December 31, 2023	As of September 30, 2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
At amortized cost		
Bank loans	263,614	356,892
Other loan in respect of sale and leaseback arrangement	15,912	10,467
	<u>279,526</u>	<u>367,359</u>
Secured	126,911	155,597
Unsecured	152,615	211,762
	<u>279,526</u>	<u>367,359</u>
The carrying amounts of the above borrowings are repayable:		
Within one year	133,751	167,749
Within a period of more than one year but not exceeding two years	74,706	127,060
Within a period of more than one year but not exceeding five years	71,069	72,550
	<u>279,526</u>	<u>367,359</u>
<i>Less: Amount due within one year shown under current liabilities</i>	<i>(133,751)</i>	<i>(167,749)</i>
	<u>145,775</u>	<u>199,610</u>

Our secured bank loans are pledged by land use rights, a building and construction in progress on the corresponding land use rights owned by us. As of December 31, 2023 and September 30, 2024, our secured bank loans pledged by land use rights amounted to RMB85.7 million and RMB83.8 million, respectively; our secured bank loans pledged by the building amounted to nil and RMB227.6 million, respectively; and the secured bank loans pledged by the construction in progress on the corresponding land use rights owned by us amounted to RMB255.5 million and RMB41.2 million, respectively. For details of our borrowings, see Note 31 to the Accountants’ Report set out in Appendix IA and Note 22 to the unaudited financial information for the nine months ended September 30, 2024 set out in Appendix IB to this document. As of November 30, 2024, we had borrowings of RMB350.2 million, of which RMB158.8 million were secured by our self-owned properties and unguaranteed, and the remaining balance of RMB191.4 million were unsecured and unguaranteed. As of November 30, 2024, we had unutilized banking facilities of RMB336.0 million.

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Some of our bank loan agreements contain standard terms, conditions and covenants that are customary for commercial bank loans in the PRC. Such covenants primarily include requirements for us to obtain the relevant lenders’ prior consent for certain transactions, such as disposal of material assets and merger or consolidation. So far as our Directors are aware, we do not have any material covenants relating to the outstanding debts which would materially limit our ability to undertake additional debt or equity financing, and there was no material breach of any covenant during the Track Record Period and up to the Latest Practicable Date.

RELATED PARTY TRANSACTIONS

Transactions With Related Parties

During the Track Record Period, we had entered into certain related party transactions. For details, see Note 36 to the Accountants’ Report set out in Appendix IA and Note 26 to the unaudited financial information for the nine months ended September 30, 2024 set out in Appendix IB to this document. During the Track Record Period, our related party transactions mainly represented our purchase of API with ancillary services and in-licenses from related parties and interests on loan from a related party. The following table sets forth a summary of our transactions with related parties during the Track Record Period.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i> <i>(unaudited)</i>	<i>RMB’000</i> <i>(unaudited)</i>
Purchase of API with ancillary services from a related party			
Shandong Topharman	10,010	9,012	1,107
In-licenses from a related party			
Topharman Shanghai	1,750	–	–
Interests on loan from a related party			
Topharman Shanghai	385	289	289
Total	<u>12,145</u>	<u>9,301</u>	<u>1,396</u>

Outstanding Balances With Related Parties

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i> <i>(unaudited)</i>
Trade payables		
Shandong Topharman	6,097	6,653
Topharman Shanghai	2,750	2,750
	8,847	9,403
Amounts due to a related party		
Topharman Shanghai ⁽¹⁾	10,882	11,171
Total	<u>19,729</u>	<u>20,574</u>

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Note:

- (1) The amounts due to Topharman Shanghai represent loan from Topharman Shanghai to Nantong Hefeng with a fixed interest rate of 3.85%. Such non-trade balance due to a related party will be settled prior to the [REDACTED].

Our Directors confirm that all material related party transactions during the Track Record Period were conducted on an arm’s length basis, and would not distort our results of operations over the Track Record Period or make our historical results over the Track Record Period not reflective of our expectations for our future performance.

CAPITAL EXPENDITURES

In 2023 and the nine months ended September 30, 2023 and 2024, our capital expenditures were RMB112.8 million, RMB78.5 million, and RMB74.6 million, respectively, which included purchase of property, plant and equipment and purchase of intangible assets. We regularly incur capital expenditures to purchase property, plant and equipment and acquire intangible assets in order to enhance our research and development capabilities and expand our business operations. The following table sets forth our capital expenditures for the year/periods indicated.

	Year Ended December 31,	Nine Months Ended September 30,	
	2023	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
		<i>(unaudited)</i>	<i>(unaudited)</i>
Purchase of property, plant and equipment	86,715	62,610	65,768
Purchase of intangible asset	26,132	15,909	8,784
Total	112,847	78,519	74,586

We anticipate incurring capital expenditures over the next few years, primarily related to the construction of our new R&D center in Suzhou and new manufacturing facility in Qingdao. We expect to fund these expenditures primarily through cash generated from operations, bank facilities, and net [REDACTED] from the [REDACTED]. Should we require additional funding for significant capital expenditures, we will explore options for equity and debt financing. The adequacy of such funding will depend on prevailing market conditions and investor sentiment toward our Company. We may also adjust our capital expenditure plans for any given period based on our development needs or in response to market conditions and other relevant factors.

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COMMITMENTS

Capital Commitments

We had the following commitments as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Capital expenditure contracted for but not provided:		
– acquisition of property, plant and equipment	100,286	257,366
Total	100,286	257,366

KEY FINANCIAL RATIO

The table below sets forth our key financial ratio as of the dates indicated.

	As of December 31,	As of September 30,
	2023	2024
Current ratio ⁽¹⁾	0.6	0.4

Note:

(1) Current ratio equals to current assets divided by current liabilities as of the same date.

Our current ratio decreased from 0.6 as of December 31, 2023 to 0.4 as of September 30, 2024, primarily due to (i) an increase in financial liabilities at amortized cost, reflecting our obligation to return the investment and the relevant interest to one of our Series C Investors with redemption rights; (ii) an increase in borrowings to support our operations; and (iii) a decrease in our trade receivables as we received certain payments from milestones and assignment of rights in relation to VV116 during the first half of 2024.

FINANCIAL RISK DISCLOSURE

Our major financial instruments include trade receivables, other receivables, bank balances and cash, trade and other payables, amounts due to a related party, lease liabilities and borrowings. We are exposed to a variety of financial risks, including market risk (currency risk and interest rate risk), credit risk and liquidity risk. The policies on how to mitigate these risks are set out below. Our management manages and monitors these exposures to ensure

FINANCIAL INFORMATION

appropriate measures are implemented on a timely and effective manner. For more details, see Note 39 to the Accountants' Report in Appendix IA to this document. As of the Latest Practicable Date, we did not hedge or consider necessary to hedge any of these risks.

Market Risks

Currency Risk

Certain financial assets and liabilities are denominated in foreign currencies of respective group entities which are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Interest Rate Risk

We are primarily exposed to fair value interest rate risk in relation to lease liabilities and fixed-rate borrowings and cash flow interest rate risk in relation to bank balances and variable-rate borrowings. We currently do not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, our management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

Credit Risks

Credit risk refers to the risk that our counterparties default on their contractual obligations resulting in financial losses to us. Our credit risk exposures are primarily attributable to trade receivables, other receivables, contract assets, amounts due from subsidiaries and bank balances. We do not hold any collateral or other credit enhancements to cover our credit risks associated with our financial assets.

Trade Receivables and Contract Assets Arising From Contracts With Customers

In order to minimize the credit risk, our management has delegated a team responsible for determination of credit limits, credit approvals and other monitoring procedures to ensure that follow-up action is taken to recover overdue debts. In this regard, our management considers that our credit risk is significantly reduced.

We perform impairment assessment under ECL model on trade receivable and contract assets balances individually and based on provision matrix. Except for items that are subject to individual evaluation, which are assessed for impairment individually, the remaining trade receivables and contract assets balances are grouped under a provision matrix based on shared credit risk characteristics by reference to repayment histories and current past due exposure for the customers.

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Other Receivables and Long-Term Deposits

For other receivables, our management makes periodic individual assessment on the recoverability of other receivables based on historical settlement records, past experience, and also quantitative and qualitative information that is reasonable and supportive forward-looking information. Our management believes that there are no significant increase in credit risk of these amounts since initial recognition and we provided impairment based on 12m ECL.

Amounts Due From Subsidiaries

For amounts due from subsidiaries, we have applied 12m ECL to measure the loss allowance. The ECL on amounts due from subsidiaries are assessed individually based on the probability of defaults of amounts due from subsidiaries, our management has taken into account the financial position of the counterparties as well as forward looking information that is available without undue cost or effort.

Bank Balances

The credit risk on bank balances and pledged bank deposits is limited because the counterparties are banks with high credit ratings assigned by international credit-rating agencies.

Liquidity risk

In the management of the liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance our operations and mitigate the effects of fluctuations in cash flows. We monitor the utilizations of bank borrowings and rely on issuance of ordinary shares and utilizations of bank facilities as significant sources of liquidity.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

During the Track Record Period and as of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

DIVIDENDS

We did not declare or pay any dividend during the Track Record Period. We do not currently have a formal dividend policy or a fixed dividend payout ratio. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make, as determined in accordance with its articles of

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association and the accounting standards and regulations in China. As advised by our PRC Legal Adviser, taking into account the aforesaid, we may not have sufficient or any distributable profits to make dividend distributions to our Shareholders in a given year, in view of our accumulated losses, or even if we become profitable, as we will only be able to declare or pay dividends out of our distributable profits until (i) the accumulated losses are covered by our after-tax profits, and (ii) sufficient statutory and other reserves are drawn in accordance with the relevant laws, regulations and our constitutional documents. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay dividends out of our profits in the foreseeable future.

DISTRIBUTABLE RESERVES

As of September 30, 2024, we did not have any distributable reserves.

PROPERTY VALUATION

AVISTA Valuation Advisory Limited, an independent property valuer, has valued our selective property interests as of November 30, 2024. Particulars of these property interests are set out in Appendix III to this document.

The table below sets out the reconciliation between the net book value of our selective property as of September 30, 2024 in the unaudited financial information for the nine months ended September 30, 2024 set out in Appendix IB to this document and the market value of our selective property as of November 30, 2024 in the Property Valuation Report set out in Appendix III to this document.

	<i>(RMB'000)</i>
Net book value of our selective property as of September 30, 2024	352,544
Depreciation for the two months ended November 30, 2024	(2,327)
Additions	16,435
Net book value as of November 30, 2024	366,652
Valuation surplus as of November 30, 2024	27,918
Valuation as of November 30, 2024 as set out in Appendix III to this document	394,570

[REDACTED]

Our [REDACTED] represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Based on the [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED]), and assuming the [REDACTED] is not exercised, our [REDACTED] in relation to the [REDACTED] are estimated to be approximately RMB[REDACTED] (HK\$[REDACTED]), representing [REDACTED]% of the gross [REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per Share and assuming the [REDACTED] is not exercised). The [REDACTED] consist of (i) [REDACTED] expenses, including [REDACTED], of approximately RMB[REDACTED] (HK\$[REDACTED]), and (ii) non-[REDACTED] expenses of approximately RMB[REDACTED] (HK\$[REDACTED]), comprising (a) fees and expenses of our legal advisers and reporting accountants of approximately RMB[REDACTED] (HK\$[REDACTED]), and (b) other fees and expenses of approximately RMB[REDACTED] (HK\$[REDACTED]).

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During the Track Record Period, we did not incur any [REDACTED]. We expect to incur [REDACTED] of approximately RMB[REDACTED] (HK\$[REDACTED]) after the Track Record Period, approximately RMB[REDACTED] (HK\$[REDACTED]) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] (HK\$[REDACTED]) of which is attributable to the issue of Shares and will be deducted from equity upon [REDACTED]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED [REDACTED] STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

[REDACTED]

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[REDACTED]

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[REDACTED]

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that there has been no material adverse change in our business, financial condition and results of operations since September 30, 2024, being the latest balance sheet date of our condensed consolidated financial statements for the nine months ended September 30, 2024 set out in Appendix IB to this document, and up to the Latest Practicable Date.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

We confirm that, as of the Latest Practicable Date, there were no circumstances that would give rise to disclosure required under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS AND PROSPECTS

See “Business — Our Strategies” for a detailed description of our future plans.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately [REDACTED], after deducting [REDACTED], fees and other estimated expenses paid and payable by us in connection with the [REDACTED], assuming the [REDACTED] being not exercised and an [REDACTED] of [REDACTED] per Share (being the [REDACTED] of the indicative [REDACTED] stated in this document). If the [REDACTED] is set at [REDACTED] per Share (being the [REDACTED] of the indicative [REDACTED]), the net [REDACTED] from the [REDACTED] will increase by approximately [REDACTED]. If the [REDACTED] is set at [REDACTED] per Share (being the [REDACTED] of the indicative [REDACTED]), the net [REDACTED] from the [REDACTED] will decrease by approximately [REDACTED].

Assuming the [REDACTED] is set at the [REDACTED] of the indicative [REDACTED] and that the [REDACTED] is not exercised, we intend to use the net [REDACTED] from the [REDACTED] for the following purposes:

1. [REDACTED]%, or approximately [REDACTED], will be used for the research and development of our Core Products, including:
 - a. [REDACTED]%, or approximately [REDACTED], will be used to fund the ongoing Phase II/III clinical trial of VV116 for the treatment of RSV infection. We expect to conclude the ongoing Phase II clinical stage of this trial in the second quarter of 2025 and initiate the Phase III clinical study in the third quarter of 2025. We expect to complete the registrational Phase III clinical study in the second half of 2026. See “Business — Innovative Drug Candidates — Core Product — VV116 — RNA-Dependent RNA Polymerase Inhibitor — Clinical Development Plan;”
 - b. [REDACTED]%, or approximately [REDACTED], will be used to fund the clinical trials of LV232 for the treatment of depressive disorder, of which:
 - i. [REDACTED]%, or approximately [REDACTED] will be used to fund the Phase II clinical trial which we plan to initiate in the first quarter of 2025, with the trial expected to be completed in the second half of 2026; and
 - ii. [REDACTED]%, or approximately [REDACTED] will be used to fund a planned Phase III clinical trial of short-term usage of LV232, which we intend to commence in the second half of 2026.

See “Business — Innovative Drug Candidates — Core Product — LV232 — Potential First-in-Class, 5-HTT/5-HT₃ Receptor Modulator — Clinical Development Plan;” and

FUTURE PLANS AND USE OF [REDACTED]

- c. [REDACTED]%, or approximately [REDACTED], will be used to fund the development of a sublingual and buccal mucosal dosage form for TPN171, and the preclinical studies to explore indication expansion opportunities for TPN171.
2. [REDACTED]%, or approximately [REDACTED], will be used for the research and development of our other product candidates, including:
 - a. [REDACTED]%, or approximately [REDACTED], will be used to fund the ongoing and planned Phase I clinical trials and a planned Phase II clinical trial of VV261 for the treatment of SFTSV. We are currently conducting a Phase I single dose-escalation study of VV261 in healthy subjects in China. Additionally, we plan to initiate a multiple dose-escalation study and a series of Phase I clinical trials to thoroughly evaluate the safety, tolerability, PK and food effects of VV261 in healthy subjects, as well as in elderly individuals, patients with mild to severe liver impairment, and patients with mild to severe renal impairment. The key clinical trials providing essential data for the initiation of a Phase II trial are anticipated to be completed in the first half of 2026. We intend to commence a Phase II clinical trial in the first half of 2027. See “Business — Innovative Drug Candidates — VV261 — RNA-Dependent RNA Polymerase Inhibitor and Broad-Spectrum Antiviral Nucleoside Prodrug — Clinical Development Plan;”
 - b. [REDACTED]%, or approximately [REDACTED], will be used to fund the planned Phase I and Phase II clinical trials of TPN102 for the treatment of epilepsy. We plan to initiate a multiple dose-escalation study and a series of Phase I clinical trials to comprehensively evaluate the safety, tolerability, PK and food effects of TPN102 in healthy subjects, as well as in elderly individuals, patients with mild to severe liver impairment, and patients with mild to severe renal impairment. The key clinical trials providing essential data for the initiation of a Phase II trial are anticipated to be completed in the second half of 2026. We intend to commence a Phase II clinical trial in the first half of 2027. See “Business — Innovative Drug Candidates — TPN102 — Voltage-gated Sodium and Calcium Channels Inhibitor — Clinical Development Plan;”
 - c. [REDACTED]%, or approximately [REDACTED], will be used to fund the ongoing and planned Phase I clinical trials and a planned Phase II clinical trial of VV119 for the treatment of schizophrenia. We are currently conducting Phase I single and multiple dose-escalation studies of VV119 in healthy subjects and adult patients with schizophrenia in China. Additionally, we plan to initiate a series of Phase I clinical trials to comprehensively evaluate the safety, tolerability, PK and food effects of VV119 in healthy subjects, as well as in elderly individuals, and patients with mild to severe liver impairment or mild to severe renal impairment. The key clinical trials providing critical data for the initiation of a Phase II trial are anticipated to be completed in the fourth quarter of 2025. We intend to commence a Phase II clinical trial in the first half of 2026. See “Business — Innovative Drug Candidates — VV119 — Multi-target Serotonin-Dopamine Activity Modulator — Clinical Development Plan;” and

FUTURE PLANS AND USE OF [REDACTED]

- d. [REDACTED]%, or approximately [REDACTED], will be used to fund the development of our preclinical-stage drug candidates towards IND submission.
3. [REDACTED]%, or approximately [REDACTED], will be used for the construction of our Qingdao Facility. Under our construction plan, our Qingdao Facility is expected to complete construction by the end of 2026. See “Business — Manufacturing — Expansion Plan;”
4. [REDACTED]%, or approximately [REDACTED] will be used for the reinforcement of our sales and marketing capabilities, including:
 - a. [REDACTED]%, or approximately [REDACTED] will be used for recruitment of additional sales and marketing personnel with extensive knowledge and experience in pharmaceutical industry; and
 - b. [REDACTED]%, or approximately [REDACTED] will be used for marketing efforts to enhance the awareness of our brand and healthcare professionals and patients’ knowledge about our products.
5. [REDACTED]%, or approximately [REDACTED], will be used for working capital and other general corporate purposes.

The above allocation of the net [REDACTED] from the [REDACTED] will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the [REDACTED] of the indicative [REDACTED] stated in this document.

We have executed an adaptive clinical development strategy and may evaluate and adjust our priorities and funding allocations for different indications or other aspects of our clinical trials for each drug candidate from time to time based on the status and results of ongoing clinical trials, while the percentages of [REDACTED] allocated to each drug candidate will generally remain stable. Therefore, the percentages and amounts of net [REDACTED] allocated to each indication, clinical trial and/or commercialization plan of each drug candidate may be subject to change.

If the [REDACTED] is exercised in full, the net [REDACTED] that we will receive will be approximately [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share (being the [REDACTED] of the indicative [REDACTED]). In the event that the [REDACTED] is exercised in full, we intent to apply the additional net [REDACTED] to the above purposes in the proportions stated above.

To the extent that the net [REDACTED] from the [REDACTED] are not immediately applied to the above purposes and to the extent permitted by applicable law and regulations, we will only deposit the net [REDACTED] in short-term interest-bearing accounts at licensed commercial banks and/or other authorized financial institutions (as defined under the Securities and Futures Ordinance or the applicable laws and regulations in other jurisdictions).

FUTURE PLANS AND USE OF [REDACTED]

In the event of any material change in our use of net [REDACTED] of the [REDACTED] from the purposes described above or in our allocation of the net [REDACTED] among the purposes described above, a formal announcement will be made.

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

The following is the text of a report set out on pages IA-1 to IA-60, received from the Company’s reporting accountants, Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.



ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF VIGONVITA LIFE SCIENCES CO., LTD. AND CITIC SECURITIES (HONG KONG) LIMITED

Introduction

We report on the historical financial information of Vigonvita Life Sciences Co., Ltd.* (“蘇州旺山旺水生物醫藥股份有限公司”) (the “Company”) and its subsidiaries (together, the “Group”) set out on pages IA-4 to IA-60, which comprises the consolidated statement of financial position of the Group as at December 31, 2023, the statement of financial position of the Company as at December 31, 2023 and the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows of the Group for the year ended December 31, 2023 (the “Track Record Period”) and material accounting policy information and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages IA-4 to IA-60 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [●] (the “Document”) in connection with the initial [REDACTED] of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2 to the Historical Financial Information, and for such internal control as the directors of the Company determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

* English name is for identification purpose only.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors of the Company, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the Group’s financial position as at December 31, 2023, of the Company’s financial position as at December 31, 2023 and of the Group’s financial performance and cash flows for the Track Record Period in accordance with the basis of preparation set out in Note 2 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page IA-4 have been made.

Dividends

We refer to Note 15 to the Historical Financial Information which states that no dividend was declared or paid by the Company in respect of the Track Record Period.

[Deloitte Touche Tohmatsu]

Certified Public Accountants

Hong Kong

[●]

HISTORICAL FINANCIAL INFORMATION OF THE GROUP

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The consolidated financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, have been prepared in accordance with the accounting policies which conform with International Financial Reporting Standards (“IFRSs”) issued by International Accounting Standards Board (the “IASB”) and were audited by us in accordance with Hong Kong Standards on Auditing issued by the HKICPA (“Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

APPENDIX IA

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	<i>NOTES</i>	Year ended December 31, 2023
		<i>RMB’000</i>
Revenue	6	199,651
Cost of sales		<u>(6,014)</u>
Gross profit		193,637
Other income	8	5,974
Other gains and losses, net	9	222
Research and development expenses		(131,297)
Administrative expenses		(51,187)
Selling expenses		(1,322)
Impairment losses under expected credit loss (“ECL”) model, net of reversal		(2,400)
[REDACTED]		[REDACTED]
Finance costs	10	<u>(7,200)</u>
Profit before tax	11	6,427
Income tax expense	12	<u>–</u>
Profit for the year		<u><u>6,427</u></u>
Other comprehensive expense		
<i>Item that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of foreign operations		<u>(285)</u>
Total comprehensive income for the year		<u><u>6,142</u></u>
Profit (loss) for the year attributable to:		
Owners of the Company		12,089
Non-controlling interests		<u>(5,662)</u>
		<u><u>6,427</u></u>
Total comprehensive income (expense) for the year attributable to:		
Owners of the Company		11,804
Non-controlling interests		<u>(5,662)</u>
		<u><u>6,142</u></u>
Earnings per share		
– Basic (RMB yuan)	14	<u><u>0.08</u></u>

APPENDIX IA

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>NOTES</i>	As at December 31, 2023
		<i>RMB’000</i>
Non-current assets		
Property, plant and equipment	<i>16</i>	309,082
Right-of-use assets	<i>17</i>	126,277
Intangible assets	<i>18</i>	68,074
Other non-current assets	<i>21</i>	<u>6,679</u>
		510,112
Current assets		
Inventories	<i>22</i>	3,209
Trade receivables	<i>23</i>	36,552
Prepayments and other receivables	<i>24</i>	6,639
Contract assets	<i>25</i>	2,414
Other current assets	<i>26</i>	21,396
Bank balances and cash	<i>27</i>	<u>95,974</u>
		166,184
Current liabilities		
Trade and other payables	<i>28</i>	123,176
Contract liabilities	<i>29</i>	6,961
Amounts due to a related party	<i>36(ii)</i>	10,882
Lease liabilities	<i>30</i>	10,860
Borrowings	<i>31</i>	133,751
Deferred income	<i>32</i>	<u>179</u>
		285,809
Net current liabilities		<u>(119,625)</u>
Total assets less current liabilities		<u>390,487</u>
Non-current liabilities		
Lease liabilities	<i>30</i>	30,642
Borrowings	<i>31</i>	145,775
Deferred income	<i>32</i>	<u>25,954</u>
		202,371
Net assets		<u>188,116</u>
Capital and reserves		
Share capital	<i>33</i>	6,361
Reserves		<u>192,733</u>
Equity attributable to owners of the Company		199,094
Non-controlling interests		<u>(10,978)</u>
Total equity		<u>188,116</u>

APPENDIX IA

ACCOUNTANTS’ REPORT

STATEMENT OF FINANCIAL POSITION OF THE COMPANY

	<i>NOTES</i>	As at December 31, 2023
		<u>RMB’000</u>
Non-current assets		
Property, plant and equipment	<i>16</i>	18,810
Right-of-use assets	<i>17</i>	62,342
Intangible assets	<i>18</i>	54,549
Amounts due from subsidiaries	<i>36(ii)</i>	142,987
Interests in subsidiaries	<i>20</i>	42,411
Other non-current assets	<i>21</i>	<u>2,695</u>
		<u>323,794</u>
Current assets		
Inventories	<i>22</i>	182
Trade receivables	<i>23</i>	51,084
Prepayments and other receivables	<i>24</i>	5,393
Contract assets	<i>25</i>	2,414
Other current assets	<i>26</i>	1,198
Bank balances and cash	<i>27</i>	<u>81,696</u>
		<u>141,967</u>
Current liabilities		
Trade and other payables	<i>28</i>	41,640
Contract liabilities	<i>29</i>	7,079
Lease liabilities	<i>30</i>	4,334
Borrowings	<i>31</i>	<u>99,252</u>
		<u>152,305</u>
Net current liabilities		<u>(10,338)</u>
Total assets less current liabilities		<u>313,456</u>
Non-current liabilities		
Lease liabilities	<i>30</i>	2,627
Borrowings	<i>31</i>	40,199
Deferred income	<i>32</i>	<u>12,900</u>
		<u>55,726</u>
Net assets		<u>257,730</u>
Capital and reserves		
Share capital	<i>33</i>	6,361
Reserves	<i>34</i>	<u>251,369</u>
Total equity		<u>257,730</u>

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Attributable to owners of the Company									
	Paid-in capital	Share capital	Capital reserve	Share premium	Share-based payments reserve	Translation reserve	(Accumulated losses) retained earnings	Subtotal	Non-controlling interests	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
As at January 1, 2023	6,361	-	348,639	-	63,320	302	(246,077)	172,545	(5,316)	167,229
Profit (loss) for the year	-	-	-	-	-	-	12,089	12,089	(5,662)	6,427
Other comprehensive expense for the year	-	-	-	-	-	(285)	-	(285)	-	(285)
Total comprehensive income (expense) for the year	-	-	-	-	-	(285)	12,089	11,804	(5,662)	6,142
Conversion into a joint stock company (Note 33)	(6,361)	6,361	(348,639)	176,701	(62,092)	-	234,030	-	-	-
Recognition of equity-settled share-based payments (Note 35)	-	-	-	-	14,745	-	-	14,745	-	14,745
As at December 31, 2023	-	6,361	-	176,701	15,973	17	42	199,094	(10,978)	188,116

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CONSOLIDATED STATEMENT OF CASH FLOWS

	Year ended December 31, 2023
	<i>RMB’000</i>
OPERATING ACTIVITIES	
Profit for the year	6,427
Adjustments for:	
Depreciation of property, plant and equipment	6,867
Amortisation of intangible assets	22
Depreciation of right-of-use assets	9,951
Share-based payment expenses	14,745
Finance costs	7,200
Impairment losses under expected credit loss model, net of reversal	2,400
Net foreign exchange gains	(246)
Operating cash flow before movements in working capital	47,366
Increase in trade receivables, prepayments and other receivables	(26,040)
Increase in inventories	(2,106)
Increase in contract assets	(2,013)
Increase in other current assets	(4,827)
Increase in other non-current assets	(3,942)
Increase in trade and other payables	16,703
Decrease in contract liabilities	(2,193)
Increase in deferred income	7,721
NET CASH FROM OPERATING ACTIVITIES	30,669
INVESTING ACTIVITIES	
Purchase of property, plant and equipment	(86,715)
Purchase of intangible assets	(26,132)
Payments for right-of-use assets	(46,360)
Payments for rental deposits	(1,664)
NET CASH USED IN INVESTING ACTIVITIES	(160,871)
FINANCING ACTIVITIES	
Interest paid	(11,797)
Proceeds from borrowings	172,348
Repayments of borrowings	(75,104)
Repayments of lease liabilities	(8,946)
NET CASH FROM FINANCING ACTIVITIES	76,501
NET DECREASE IN CASH AND CASH EQUIVALENTS	(53,701)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	149,429
Effect of foreign exchange rate changes	246
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	95,974

NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. GENERAL INFORMATION

The Company was incorporated in the People’s Republic of China (the “PRC”) on January 21, 2013 as a limited liability company. On March 10, 2023, the Company was converted to a joint stock company with limited liability under the Company Law of the PRC. The respective address of the registered office and the principal place of business of the Company are set out in the section headed “Corporate Information” to the document dated [●] (the “Document”).

The Group is an innovation-driven biopharmaceutical company dedicated to meeting clinical needs in the treatment of neuropsychiatric, infectious and andrological diseases. Particulars and principal activities of the subsidiaries are disclosed in Note 41.

The controlling shareholders of the Company are Dr. Shen Jingshan (“Dr. Shen”) and his spouse, Ms. Jin Jie. Dr. Shen is also one of the founders of the Company.

The Historical Financial Information is presented in RMB, which is also the functional currency of the Company.

2. BASIS OF PREPARATION OF THE HISTORICAL FINANCIAL INFORMATION

The Historical Financial Information has been prepared based on the accounting policies which conform with IFRSs issued by the IASB.

The statutory financial statements of the Company for the year ended December 31, 2023 were prepared in accordance with Accounting Standards for Business Enterprises of the PRC and were audited by Suzhou Fangben Certified Public Accountants Suzhou Industrial Park Branch* (蘇州方本會計師事務所有限公司園區分所), CPA registered in the PRC.

Going concern assessment

As at December 31, 2023, the Group’s net current liabilities were RMB119,625,000. Meanwhile, the Group’s total borrowings amounted to RMB279,526,000 as at December 31, 2023, of which RMB133,751,000 will be due for repayment within the next twelve months. In addition, the Group’s bank balances and cash were amounted to RMB95,974,000, whilst the Group’s current liabilities were amounted to RMB285,809,000 as at December 31, 2023.

Since (i) the Company had completed a new round of financing and received total proceeds of RMB160,000,000 during the year ended 2024, and (ii) the Group had available unutilised bank facilities of RMB349,000,000 as at December 31, 2023, which could be utilised for the expenditure on construction in progress in Suzhou. The directors of the Company have reviewed the Group’s cash flow projections prepared by the management of the Company, which cover a period of not less than twelve months from the end of the reporting period. They are of the opinion that, taking into account the above proceeds of financing and unutilised bank facilities, the Group would have sufficient working capital to fund its operations and to meet its payment obligations including the milestone payment of in-licenses and capital commitment when they fall due within twelve months from December 31, 2023. Accordingly, the directors of the Company are satisfied that it is appropriate to prepare the Historical Financial Information of the Group for the year ended December 31, 2023 on a going concern basis.

* English name is for identification purpose only.

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3. ADOPTION OF NEW AND AMENDMENTS TO IFRSs

For the purpose of preparing and presenting the Historical Financial Information for the Track Record Period, the Group has consistently applied the accounting policies which conform with IFRSs, which are effective for the accounting period beginning on January 1, 2024 throughout the Track Record Period.

New and amendments to IFRSs in issue but not yet effective

At the date of this report, the following new and amendments to IFRSs have been issued which are not yet effective:

Amendments to IFRS 9 and IFRS 7	Amendments to the Classification and Measurement of Financial Instruments ³
Amendments to IFRS 9 and IFRS 7	Contracts Referencing Nature — dependent Electricity ³
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ¹
Amendments to IFRS Accounting Standards	Annual Improvements to IFRS Accounting Standards — Volume 11 ³
Amendments to IAS 21	Lack of Exchangeability ²
IFRS 18	Presentation and Disclosure in Financial Statements ⁴

¹ Effective for annual periods beginning on or after a date to be determined

² Effective for annual periods beginning on or after 1 January 2025

³ Effective for annual periods beginning on or after 1 January 2026

⁴ Effective for annual periods beginning on or after 1 January 2027

Except for the new and amendments to IFRSs mentioned below, the directors of the Company anticipate that the application of these new and amendments to IFRSs will have no material impact on the Group’s consolidated financial statements in the foreseeable future.

IFRS 18 Presentation and Disclosure in Financial Statements

IFRS 18 Presentation and Disclosure in Financial Statements, which sets out requirements on presentation and disclosures in financial statements, will replace IAS 1 Presentation of Financial Statements. This new IFRS Accounting Standard, while carrying forward many of the requirements in IAS 1, introduces new requirements to present specified categories and defined subtotals in the statement of profit or loss; provide disclosures on management-defined performance measures in the notes to the financial statements and improve aggregation and disaggregation of information to be disclosed in the financial statements. In addition, some IAS 1 paragraphs have been moved to IAS 8 and IFRS 7. Minor amendments to IAS 7 Statement of Cash Flows and IAS 33 Earnings per Share are also made.

IFRS 18, and amendments to other standards, will be effective for annual periods beginning on or after 1 January 2027, with early application permitted. The application of the new standard is expected to affect the presentation of the statement of profit or loss and disclosures, but have no material impact on the Group’s financial position and performance.

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ACCOUNTANTS’ REPORT

4. MATERIAL ACCOUNTING POLICY INFORMATION

The Historical Financial Information has been prepared in accordance with IFRSs issued by the IASB. For the purpose of preparation of the Historical Financial Information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the Historical Financial Information includes the applicable disclosures required by the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited and by the Hong Kong Companies Ordinance.

Basis of consolidation

The Historical Financial Information incorporates the financial statements of the Company and entities controlled by the Company and its subsidiaries. Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statements of profit or loss and other comprehensive income from the date the Group gains control until the date when the Group ceases to control the subsidiary.

Profit or loss and each item of other comprehensive income are attributed to the owners of the Company and to the non-controlling interests. Total comprehensive income of subsidiaries is attributed to the owners of the Company and to the non-controlling interests even if this results in the non-controlling interests having a deficit balance.

When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies in line with the Group’s accounting policies.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

Non-controlling interests in subsidiaries are presented separately from the Group’s equity therein, which represent present ownership interests entitling their holders to a proportionate share of net assets of the relevant subsidiaries upon liquidation.

Changes in the Group’s interests in existing subsidiaries

Changes in the Group’s interests in subsidiaries that do not result in the Group losing control over the subsidiaries are accounted for as equity transactions. The carrying amounts of the Group’s relevant components of equity and the non-controlling interests are adjusted to reflect the changes in their relative interests in the subsidiaries, including re-attribution of relevant reserves between the Group and the non-controlling interests according to the Group’s and the non-controlling interests’ proportionate interests.

Any difference between the amount by which the non-controlling interests are adjusted, and the fair value of the consideration paid or received is recognised directly in equity and attributed to owners of the Company.

Interests in subsidiaries

Interests in subsidiaries are stated in the statement of financial position of the Company at cost less identified impairment loss, if any.

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ACCOUNTANTS’ REPORT

Revenue from contracts with customers

Information about the Group’s accounting policies relating to contracts with customers is provided in Notes 6, 25 and 29.

Property, plant and equipment

Property, plant and equipment are tangible assets that are held for use in the production or supply of goods or services, or for administrative purposes other than construction in progress as described below are stated in the consolidated statement of financial position at cost less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

Property, plant and equipment in the course of construction for production, supply or administrative purposes are carried at cost, less any recognised impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management, including costs of testing whether the related assets are functioning properly and, for qualifying assets, borrowing costs capitalised in accordance with the Group’s accounting policy. Depreciation of these assets, on the same basis as other property assets, commences when the assets are ready for their intended use.

Depreciation is recognised so as to write off the cost of assets other than properties under construction less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property, plant and equipment is derecognised upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognised in profit or loss.

Leases

The Group assesses whether a contract is or contains a lease based on the definition under IFRS 16 at inception of the contract. Such contract will not be reassessed unless the terms and conditions of the contract are subsequently changed.

The Group as a lessee

Allocation of consideration to components of a contract

For a contract that contains a lease component and one or more additional lease or non-lease components, the Group allocates the consideration in the contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

Non-lease components are separated from lease component and are accounted for by applying other applicable standards.

Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option. It also applies the recognition exemption for lease of low-value assets. Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis or another systematic basis over the lease term.

Right-of-use assets

The cost of right-of-use assets includes:

- the amount of the initial measurement of the lease liability; and
- any lease payments made at or before the commencement date, less any lease incentives received.

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ACCOUNTANTS’ REPORT

Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

Right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

The Group presents right-of-use assets as a separate line item on the consolidated statement of financial position.

Refundable rental deposits

Refundable rental deposits paid are accounted under IFRS 9 and initially measured at fair value. Adjustments to fair value at initial recognition are considered as additional lease payments and included in the cost of right-of-use assets.

Lease liabilities

At the commencement date of a lease, the Group recognises and measures the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable.

After the commencement date, lease liabilities are adjusted by interest accretion and lease payments.

The Group remeasures lease liabilities (and makes a corresponding adjustment to the related right-of-use assets) whenever:

- the lease term has changed or there is a change in the assessment of exercise of a purchase option, in which case the related lease liability is remeasured by discounting the revised lease payments using a revised discount rate at the date of reassessment.
- a lease contract is modified and the lease modification is not accounted for as a separate lease (see below for the accounting policy for “lease modifications”).

The Group presents lease liabilities as a separate line item on the consolidated statement of financial position.

Lease modifications

The Group accounts for a lease modification as a separate lease if:

- the modification increases the scope of the lease by adding the right to use one or more underlying assets; and
- the consideration for the leases increases by an amount commensurate with the stand-alone price for the increase in scope and any appropriate adjustments to that stand-alone price to reflect the circumstances of the particular contract.

For a lease modification that is not accounted for as a separate lease, the Group remeasures the lease liability based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

The Group accounts for the remeasurement of lease liabilities by making corresponding adjustments to the relevant right-of-use asset. When the modified contract contains a lease component and one or more additional lease or non-lease components, the Group allocates the consideration in the modified contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

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ACCOUNTANTS’ REPORT

Sale and leaseback transactions

The Group applies the requirements of IFRS 15 *Revenue from Contracts with Customers* to assess whether sale and leaseback transaction constitutes a sale by the Group.

The Group as a seller-lessee

For a transfer that does not satisfy the requirements as a sale, the Group as a seller-lessee continues to recognise the assets and accounts for the transfer proceeds as borrowings within the scope of IFRS 9.

Intangible assets

Intangible assets acquired separately

Intangible assets with finite useful lives that are acquired separately are carried at costs less accumulated amortisation and any accumulated impairment losses. Amortisation for intangible assets with finite useful lives is recognised on a straight-line basis over their estimated useful lives. The estimated useful life and amortisation method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

Internally-generated intangible assets – research and development expenditure

Expenditure on research activities is recognised as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities (or from the development phase of an internal project) is recognised if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognised for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. The Group recognises development costs as follows:

For class I innovative drugs (innovative drugs that have not been previously approved for marketing in Mainland China), development stage begins after obtaining new drug application approval from drug regulatory organisation. Development costs at this stage are recognised as assets when the above six criteria are met.

For generic drugs which have been previously approved for marketing in Mainland China, development stage begins after commencement of bioequivalence tests. Development costs incurred for bioequivalence tests are recognised as assets when the above six criteria are met. Where no internally-generated intangible asset can be recognised, development expenditure is recognised in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortisation and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

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An intangible asset is derecognised on disposal, or when no future economic benefits are expected from use or disposal. Gains and losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognised in profit or loss when the asset is derecognised.

Impairment on property, plant and equipment and right-of-use assets and intangible assets

At the end of each reporting period, the Group reviews the carrying amounts of its property, plant and equipment and right-of-use assets to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any). Intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that may be impaired.

The recoverable amount of property, plant and equipment, right-of-use assets and intangible assets are estimated individually. When it is not possible to estimate the recoverable amount individually, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing the recoverable amount, the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, the Group compares the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash-generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognised immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset (or a cash-generating unit) in prior years. A reversal of an impairment loss is recognised immediately in profit or loss.

Borrowing costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, which are assets that necessarily take a substantial period of time to get ready for their intended use or sale, are added to the cost of those assets until such time as the assets are substantially ready for their intended use or sale.

Any specific borrowing that remain outstanding after the related asset is ready for its intended use or sale is included in the general borrowing pool for calculation of capitalisation rate on general borrowings. Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs eligible for capitalisation.

All other borrowing costs are recognised in profit or loss in the period in which there are incurred.

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Government grants

Government grants are not recognised until there is reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received.

Government grants are recognised in profit or loss on a systematic basis over the periods in which the Group recognises as expenses the related costs for which the grants are intended to compensate. Specifically, government grants whose primary condition is that the Group should purchase, construct or otherwise acquire non-current assets are recognised as deferred income in the consolidated statement of financial position and transferred to profit or loss on a systematic and rational basis over the useful lives of the related assets.

Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognised in profit or loss in the period in which they become receivable. Such grants are presented under “other income”.

Employee benefits

Retirement benefit costs

Payments to defined contribution retirement benefit plans including state-managed retirement benefit schemes in the PRC are recognised as an expense when employees have rendered service entitling them to the contributions.

Termination benefits

A liability for a termination benefit is recognised at the earlier of when the Group entity can no longer withdraw the offer of the termination benefit and when it recognises any related restructuring costs.

Short-term employee benefits

Short-term employee benefits are recognised at the undiscounted amount of the benefits expected to be paid as and when employees rendered the services. All short-term employee benefits are recognised as an expense unless another IFRS requires or permits the inclusion of the benefit in the cost of an asset.

A liability is recognised for benefits accruing to employees (such as wages and salaries) after deducting any amount already paid.

Share-based payment

Equity-settled share-based payment transactions

Restricted shares (“RS”) granted to employees

Equity-settled share-based payments to employees are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on the Group’s estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payments reserve). At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognised in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payments reserve.

When shares granted are vested, the amount previously recognised in share-based payments reserve will be transferred to share premium.

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Taxation

Income tax expense represents the sum of current and deferred income tax expense.

The tax currently payable is based on taxable profit for the year. Taxable profit differs from profit before tax because of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Group's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax is recognised on temporary differences between the carrying amounts of assets and liabilities in the Historical Financial Information and the corresponding tax bases used in the computation of taxable profit. Deferred tax liabilities are generally recognised for all taxable temporary differences. Deferred tax assets are generally recognised for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilised. Such deferred tax assets and liabilities are not recognised if the temporary difference arises from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit and at the time of the transaction does not give rise to equal taxable and deductible temporary differences. In addition, deferred tax liabilities are not recognised if the temporary difference arises from the initial recognition of goodwill.

Deferred tax liabilities are recognised for taxable temporary differences associated with investments in subsidiaries, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with such investments and interests are only recognised to the extent that it is probable that there will be sufficient taxable profits against which to utilise the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset is realised, based on tax rate (and tax laws) that have been enacted or substantively enacted by the end of each reporting period.

The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of each reporting period, to recover or settle the carrying amount of its assets and liabilities.

For the purposes of measuring deferred tax for leasing transactions in which the Group recognises the right-of-use assets and the related lease liabilities, the Group first determines whether the tax deductions are attributable to the right-of-use assets or the lease liabilities.

For leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 *Income Taxes* requirements to the lease liabilities and the related assets separately. The Group recognises a deferred tax asset related to lease liabilities to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilised and a deferred tax liability for all taxable temporary differences.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income tax levied to the same taxable entity by the same taxation authority.

Current and deferred tax are recognised in profit or loss, except when they relate to items that are recognised in other comprehensive income or directly in equity, in which case, the current and deferred tax are also recognised in other comprehensive income or directly in equity respectively.

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Cash and cash equivalents

Cash and cash equivalents presented on the consolidated statement of financial position include:

- cash, which comprises of cash on hand and demand deposits; and
- cash equivalents, which comprises of short-term (generally with original maturity of three months or less), highly liquid investments that are readily convertible to a known amount of cash and which are subject to an insignificant risk of changes in value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes.

For the purposes of the consolidated statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above.

Financial instruments

Financial assets and financial liabilities are recognised when a group entity becomes a party to the contractual provisions of the instrument. All regular way purchases or sales of financial assets are recognised and derecognised on a trade date basis. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the time frame established by regulation or convention in the market place.

Financial assets and financial liabilities are initially measured at fair value except for trade receivable arising from contracts with customers which are initially measured in accordance with IFRS 15. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities (other than financial assets and financial liabilities at fair value through profit or loss (“FVTPL”)) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transaction costs directly attributed to the acquisition of financial assets or financial liabilities at FVTPL are recognised immediately in profit or loss.

The effective interest method is a method of calculating the amortised cost of a financial asset or financial liability and of allocating interest income and interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts and payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial asset or financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

Financial assets

Classification and subsequent measurement of financial assets

Financial assets that meet the following conditions are subsequently measured at amortised cost:

- the financial asset is held within a business model whose objective is to collect contractual cash flows; and
- the contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

All other financial assets are subsequently measured at FVTPL.

(i) Amortised cost and interest income

Interest income is recognised using the effective interest method for financial assets measured subsequently at amortised cost and calculated by applying the effective interest rate to the gross carrying amount of a financial asset, except for financial assets that have subsequently become credit-impaired (see below). For financial assets that have subsequently become credit-impaired, interest income is recognised by applying the effective interest rate to the amortised cost of the financial asset from the next reporting period. If the credit risk on the credit-impaired financial instrument improves so that the financial asset is no longer credit-impaired, interest income is recognised by applying the effective interest rate to the gross carrying amount of the financial asset from the beginning of the reporting period following the determination that the asset is no longer credit-impaired.

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(ii) Financial assets at FVTPL

Financial assets that do not meet the criteria for being measured at amortised cost are measured at FVTPL.

Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognised in profit or loss. The net gain or loss recognised in profit or loss includes any interest earned on the financial asset and is included in the “other gains and losses, net” line item.

Impairment of financial assets and contract assets subject to impairment assessment under IFRS 9

The Group performs impairment assessment under expected credit losses (“ECL”) model on financial assets (including trade receivables, other receivables, bank balances and amounts due from subsidiaries) and contract assets which are subject to impairment assessment under IFRS 9. The amount of ECL is updated at each reporting date to reflect changes in credit risk since initial recognition.

Lifetime ECL represents the ECL that will result from all possible default events over the expected life of the relevant instrument. In contrast, 12-month ECL (“12m ECL”) represents the portion of lifetime ECL that is expected to result from default events that are possible within 12 months after each reporting date. Assessments are done based on the Group’s historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current conditions at the reporting date as well as the forecast of future conditions.

The Group always recognises lifetime ECL for trade receivables and contract assets.

For all other instruments, the Group measures the loss allowance equal to 12m ECL, unless there has been a significant increase in credit risk since initial recognition, in which case the Group recognises lifetime ECL. The assessment of whether lifetime ECL should be recognised is based on significant increases in the likelihood or risk of a default occurring since initial recognition.

(i) Significant increase in credit risk

In assessing whether the credit risk has increased significantly since initial recognition, the Group compares the risk of a default occurring on the financial instrument as at each reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition. In making this assessment, the Group considers both quantitative and qualitative information that is reasonable and supportable, including historical experience and forward-looking information that is available without undue cost or effort.

In particular, the following information is taken into account when assessing whether credit risk has increased significantly:

- an actual or expected significant deterioration in the financial instrument’s external (if available) or internal credit rating;
- significant deterioration in external market indicators of credit risk, e.g. a significant increase in the credit spread, the credit default swap prices for the debtor;
- existing or forecast adverse changes in business, financial or economic conditions that are expected to cause a significant decrease in the debtor’s ability to meet its debt obligations;
- an actual or expected significant deterioration in the operating results of the debtor;
- an actual or expected significant adverse change in the regulatory, economic, or technological environment of the debtor that results in a significant decrease in the debtor’s ability to meet its debt obligations.

Irrespective of the outcome of the above assessment, the Group presumes that the credit risk has increased significantly since initial recognition when contractual payments are more than 30 days past due, unless the Group has reasonable and supportable information that demonstrates otherwise.

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The Group regularly monitors the effectiveness of the criteria used to identify whether there has been a significant increase in credit risk and revises them as appropriate to ensure that the criteria are capable of identifying significant increase in credit risk before the amount becomes past due.

(ii) Definition of default

For internal credit risk management, the Group considers an event of default occurs when information developed internally or obtained from external sources indicates that the debtor is unlikely to pay its creditors, including the Group, in full (without taking into account any collaterals held by the Group).

(iii) Credit-impaired financial assets

A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. Evidence that a financial asset is credit-impaired includes observable data about the following events:

- (a) significant financial difficulty of the issuer or the borrower;
- (b) a breach of contract, such as a default or past due event;
- (c) the lender(s) of the borrower, for economic or contractual reasons relating to the borrower’s financial difficulty, having granted to the borrower a concession(s) that the lender(s) would not otherwise consider; or
- (d) it is becoming probable that the borrower will enter bankruptcy or other financial reorganisation.

(iv) Write-off policy

The Group writes off a financial asset when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, for example, when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings, whichever occurs sooner. Financial assets written off may still be subject to enforcement activities under the Group’s recovery procedures, taking into account legal advice where appropriate. A write-off constitutes a derecognition event. Any subsequent recoveries are recognised in profit or loss.

(v) Measurement and recognition of ECL

The measurement of ECL is a function of the probability of default, loss given default (i.e. the magnitude of the loss if there is a default) and the exposure at default. The assessment of the probability of default and loss given default is based on historical data and forward-looking information. Estimation of ECL reflects an unbiased and probability-weighted amount that is determined with the respective risks of default occurring as the weights. Except for those trade receivables of significant balances or with different risk characteristics, the Group uses a practical expedient in estimating ECL on trade receivables collectively and taking into consideration historical credit loss experience and forward looking information that is available without undue cost or effort.

Generally, the ECL is the difference between all contractual cash flows that are due to the Group in accordance with the contract and the cash flows that the Group expects to receive, discounted at the effective interest rate determined at initial recognition.

Lifetime ECL for trade receivables and contract assets for contract research organisation (“CRO”) services are considered on a collective basis taking into consideration past due information and relevant credit information such as forward-looking macroeconomic information.

For collective assessment, the Group takes into consideration the following characteristics when formulating the grouping:

- Past-due status;
- Nature, size and industry of debtors; and
- External credit ratings where available.

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The grouping is regularly reviewed by management to ensure the constituents of each group continue to share similar credit risk characteristics.

Interest income is calculated based on the gross carrying amount of the financial asset unless the financial asset is credit-impaired, in which case interest income is calculated based on amortised cost of the financial asset.

The Group recognises an impairment gain or loss in profit or loss for all financial instruments by adjusting their carrying amount, with the exception of trade receivables, contract assets, other receivables and amounts due from subsidiaries, where the corresponding adjustment is recognised through a loss allowance account.

Foreign exchange gains and losses

The carrying amount of financial assets that are denominated in a foreign currency is determined in that foreign currency and translated at the spot rate at the end of each reporting period. Specifically:

For financial assets measured at amortised cost that are not part of a designated hedging relationship, exchange differences are recognised in profit or loss in the “other gains and losses, net” line item (Note 9) as part of the net foreign exchange gains/(losses).

Derecognition of financial assets

The Group derecognises a financial asset only when the contractual rights to the cash flows from the assets expire.

On derecognition of a financial asset measured at amortised cost, the difference between the asset’s carrying amount and the sum of the consideration received and receivable is recognised in profit or loss.

Financial liabilities and equity

Classification as debt or equity

Debt and equity instruments are classified as either financial liabilities or as equity in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognised at the proceeds received, net of direct issue costs.

Financial liabilities

All financial liabilities are subsequently measured at amortised cost using the effective interest method.

Financial liabilities at amortised cost

Financial liabilities including trade and other payables, amounts due to a related party and borrowings are subsequently measured at amortised cost, using the effective interest method.

Derecognition of financial liabilities

The Group derecognises financial liabilities when, and only when, the Group’s obligations are discharged, cancelled or have expired. The difference between the carrying amount of the financial liability derecognised and the consideration paid and payable is recognised in profit or loss.

Offsetting a financial asset and a financial liability

A financial asset and a financial liability are offset and the net amount presented in the consolidated statement of financial position when, and only when, the Group currently has a legally enforceable right to set off the recognised amounts; and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

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Inventories

Inventories are stated at the lower of cost and net realisable value. Costs of inventories are determined on a first-in, first-out method. Net realisable value represents the estimate selling price for inventories less all estimated costs of completion and costs necessary to make the sale. Costs necessary to make the sale include incremental costs directly attributable to the sale and non-incremental costs which the Group must incur to make the sale.

Foreign currencies

In preparing the financial statements of each individual group entity, transactions in currencies other than the functional currency of that entity (foreign currencies) are recognised at the rates of exchanges prevailing on the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are recognised in profit or loss in the period in which they arise, except for exchange differences on monetary items receivable from or payable to a foreign operation for which settlement is neither planned nor likely to occur (therefore forming part of the net investment in the foreign operation), which are recognised initially in other comprehensive income.

For the purposes of presenting the Historical Financial Information, the assets and liabilities of the Group’s operations are translated into the presentation currency of the Group (i.e. RMB) using exchange rates prevailing at the end of each reporting period. Income and expenses items are translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the date of transactions are used. Exchange differences arising, if any, are recognised in other comprehensive income and accumulated in equity under the heading of translation reserve (attributed to non-controlling interests as appropriate).

5. CRITICAL ACCOUNTING JUDGMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

In the application of the Group’s accounting policies, which are described in Note 4, the directors of the Company are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and underlying assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Critical judgements in applying accounting policies

The following are the critical judgements, apart from those involving estimations (see below), that the directors of the Company have made in the process of applying the Group’s accounting policies and that have the most significant effect on the amounts recognised in the consolidated financial statements.

Research and development expenses

Development expenses incurred on the Group’s drug product pipelines are capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group’s intention to complete and the Group’s ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development expenses which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria are met for capitalisation.

During the year ended December 31, 2023, the Group incurred significant research and development expenses of RMB141,491,000 (before capitalisation and excluding purchase of in-licenses), out of which, development costs amounted to RMB10,194,000 have been capitalised and research and development expenses amounted to RMB131,297,000 are expensed when incurred. As at December 31, 2023, the capitalised development costs of the Group and the Company were RMB16,408,000 and RMB15,823,000, respectively.

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Key sources of estimation uncertainty

The following are the key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Impairment testing of intangible assets not ready for use

Capitalised development costs and in-licenses are recognised as intangible assets and stated at cost less accumulated amortization and impairment, if any. For the capitalised development costs and in-licenses not yet available for use, the Group would assess the assets individually for impairment annually. When it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which the assets belongs. In determining whether an asset is impaired, the Group has to exercise judgment and make estimation, particularly in assessing: (1) whether the carrying value of an asset can be supported by the recoverable amount, which is the higher of the value in use or fair value less costs of disposal; and (2) the appropriate key assumptions to be applied in estimating the recoverable amounts including cash flow projections and an appropriate discount rate. Changing the assumptions and estimates as set out in Note 19 to the Historical Financial Information in the cash flow projections, could materially affect the net present value used in the impairment test.

As at December 31, 2023, the carrying amounts of capitalised development costs and in-licenses not yet available for use are RMB67,688,000 (net of accumulated impairment loss of RMB2,500,000). Details of the assessment of impairment of intangible assets not yet available for use are set out in Note 19 to the Historical Financial Information.

6. REVENUE

(i) Disaggregation of revenue from contracts with the customers:

	Year ended December 31, 2023
	<i>RMB'000</i>
Timing of revenue recognition	
<i>At a point in time</i>	
Out-licensing income	196,157
Sales of pharmaceutical products	674
	196,831
<i>Over time</i>	
CRO services	2,820
	199,651
Geographical market	
The PRC	198,977
Uzbekistan	674
	199,651

(ii) Performance obligations for contracts with customers and revenue recognition policies

Out-licensing income

From 2021 to 2023, the Company entered into an out-licensing agreement and several supplementary agreements with customers to grant them (i) an exclusive right of research and development, production, and commercialisation of Project VV116 applying to COVID-19 symptoms and (ii) an exclusive supply right of pharmaceutical ingredient for Project VV116 applying to COVID-19 symptoms in the world except for five countries in Central Asia (comprising Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan), North Africa (comprising Egypt, Libya, Tunisia, Algeria, Morocco, and Sudan), the Middle East (comprising Saudi Arabia, Iran, Iraq, Kuwait, United Arab Emirates, Oman, Qatar, Bahrain, Turkey, Israel, Palestine, Syria, Lebanon, Jordan, Yemen, Cyprus, Georgia, Armenia, and Azerbaijan), and Russia (the “Granted Regions”).

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The consideration for the out-licensing comprises of (i) development milestones payments, (ii) royalties calculated based on the higher of sales or gross profits as defined in the related supplementary agreement with customers, and (iii) a consideration for the exclusive supply right of the pharmaceutical ingredient for Project VV116 applying to COVID-19 symptoms in the Granted Regions.

The fee for the exclusive supply right of the pharmaceutical ingredient for Project VV116 applying to COVID-19 symptoms in the Granted Regions is recognised as revenue when the control of the supply right is obtained by the customer. Installment payment of total consideration was settled within one year after control of the supply right transferred, the Group applies the practical expedient of not adjusting the transaction price for any significant financing component.

For variable consideration in relation to milestone payments and royalties from out-licensing agreement, the Group estimates the amount of consideration to which it will be entitled using the most likely amount, which best predicts the amount of consideration to which the Group will be entitled. The potential milestone payments that the Company is eligible to receive were considered as variable consideration as all milestone amounts were fully constrained due to uncertainty of achievement. The estimated amount of variable consideration is included in the transaction price only to the extent that it is highly probable that such an inclusion will not result in a significant revenue reversal in the future when the uncertainty associated with the variable consideration is subsequently resolved.

At the end of each reporting period, the Group updates the estimated transaction price (including updating its assessment of whether an estimate of variable consideration is constrained) to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period.

The aforementioned milestone payments, royalties and the exclusive supply right of the pharmaceutical ingredient of RMB196,157,000 are recognised as revenue for the year ended December 31, 2023. As at December 31, 2023, the remaining uncompleted milestone payments are subject to the future achievement of remaining milestone criteria.

CRO services

The Group earns revenues by providing CRO services to its customers through fee-for-service (“FFS”) contracts. The Group carries out several research services including managing pre-clinical studies and preparing relevant application documents for its customers to ensure the research meet all regulatory guidelines. The Group identifies all services as one performance obligation and recognises FFS revenue of contractual elements over time as the Group’s performance does not create an asset with an alternative future use since the Group cannot redirect the asset for use on another customer, and the contract terms specify the Group has an enforceable right to payment for performance completed to date. And the Group uses the input method to determine the progress of performance based on the percentage of costs incurred to date to the total estimated costs for the completion of the performance obligation.

The transaction price received by the Group is recognised as a contract liability until the services have been delivered to the customers.

Sales of pharmaceutical products

Revenue is recognised when control of the goods has been transferred, being when the goods have been delivered to the customers’ specific locations and the customers have inspected and accepted the goods. Transportation and handling activities that occur before customers obtain control are considered as fulfilment activities. A receivable is recognised by the Group when the control of goods are transferred to the customers. The normal credit term is 30 to 60 days upon the control of goods are transferred to the customers. The transaction price received by the Group is recognised as a contract liability until the control of goods are transferred to the customers.

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(iii) Transaction price allocated to the remaining performance obligation for contracts with customers

The transaction price allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December 2023 and the expected timing of recognising revenue are as follows:

	<u>CRO services</u>
	<i>RMB’000</i>
Within one year	4,780
More than one year	717
	<u>5,497</u>

Since the timing of the services to be performed are not subject to contract terms, the above information was based on management’s estimate as at December 31, 2023, and the actual timing of revenue recognition may change, depending on the actual progress of pre-clinical studies. These amounts disclosed above do not include transaction price allocated to performance obligations which have been satisfied but not yet recognised due to variable consideration constraint.

All sales of pharmaceutical products are for a period of one year or less. As permitted under IFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

7. SEGMENTS INFORMATION

For the purpose of resources allocation and performance assessment, the general manager of the Company, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole. The Group has only one reportable segment. Accordingly, only geographical information and major customers are presented.

Geographical information

The Group’s operations are located in the PRC and Uzbekistan.

Information about the Group’s revenue from continuing operations from external customers is presented based on the location of the operations. Details of geographical information are set out in Note 6(i) to the Historical Financial Information.

Information about major customers

Revenue from customers contributing over 10% of the total revenue of the Group during the Track Record Period are as follows:

	<u>Year ended</u> <u>December 31, 2023</u>
	<i>RMB’000</i>
Customer A	102,102
Customer B	94,340
	<u>196,442</u>

8. OTHER INCOME

	<u>Year ended</u> <u>December 31, 2023</u>
	<i>RMB’000</i>
Government grants (<i>Note</i>)	3,988
Bank interest income	1,792
Others	194
	<u>5,974</u>

Note: The amount represents subsidies granted by the PRC government authorities as incentives mainly for the Group’s research and development activities. The government grants including unconditional and conditional which had been approved by the PRC government authorities. The unconditional government grants are recognised when payments were received. The conditional government grants are recognised when condition met and the corresponding grants are received.

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9. OTHER GAINS AND LOSSES, NET

	Year ended December 31, 2023
	<i>RMB’000</i>
Net foreign exchange gains	246
Others	<u>(24)</u>
	<u>222</u>

10. FINANCE COSTS

	Year ended December 31, 2023
	<i>RMB’000</i>
Interest on borrowings	10,796
Less: amounts capitalised in the cost of construction in progress	<u>5,386</u>
	5,410
Interest on lease liabilities	1,405
Interest on loan from a related party (<i>Note 36(i)</i>)	<u>385</u>
	<u>7,200</u>

11. PROFIT BEFORE TAX

Profit before tax for the year has been arrived at after charging:

	Year ended December 31, 2023
	<i>RMB’000</i>
Depreciation of property, plant and equipment	6,867
Depreciation of right-of-use assets	10,926
Amortisation of intangible assets	<u>22</u>
Total depreciation and amortisation	17,815
Less: amounts capitalised in the cost of construction in progress	<u>975</u>
	<u>16,840</u>
Auditors’ remuneration	800
Impairment losses recognised (reversed) on	
– trade receivables	1,683
– other receivables	(183)
– contract assets	900
Cost of inventories recognised as an expense	
– research and development expenses	10,707
– costs of sales	775
Directors’ and supervisors’ emoluments (<i>Note 13(a)</i>)	17,327
Other staff costs:	
– salaries and other benefits	54,716
– discretionary bonus (<i>Note</i>)	2,655
– retirement benefit scheme contributions	<u>6,284</u>
Total staff costs (including directors’ emoluments)	<u>80,982</u>

Note: Discretionary bonus is determined based on their duties and responsibilities of the relevant individuals within the Group and the Group’s performance.

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12. INCOME TAX EXPENSE

(i) Income tax expense:

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the tax rate of the PRC subsidiaries of the Company is 25% during the year ended December 31, 2023.

The Company was accredited as a “High and New Technology Enterprises” on November 18, 2022 and it may entitle to a preferential tax rate of 15% for a three-year period commencing from the year of accreditation, subject to certain conditions. Accordingly, the applicable Enterprise Income Tax rate (the “EIT rate”) of the Company for the year ended 31 December 2023 is 15%.

Pursuant to Caishui 2023 circular No. 7, the Company enjoyed super deduction of 200% on qualified research and development expenditures for the year ended December 31, 2023.

Vigonvita Tashkent, a wholly-owned subsidiary of the Company, is subject to the Uzbekistan Corporate Income Tax rate of 15% for the year ended December 31, 2023.

No provision for taxation in the PRC or Uzbekistan has been made as the Group’s has no taxable profit for the year ended December 31, 2023.

The income tax expense for the year ended December 31, 2023 can be reconciled to the profit before tax per the consolidated statements of profit or loss and other comprehensive expenses as follows:

	Year ended December 31, 2023
	<i>RMB’000</i>
Profit before tax	6,427
PRC income tax rate at 25%	1,607
Tax effect of expenses that are not deductible for tax purpose	363
Tax effect of super deduction on research and development expenses	(28,590)
Tax effect of tax losses not recognised	20,560
Tax effect of deductible temporary differences not recognised	6,328
Utilisation of deductible temporary differences previously not recognised	(268)
Income tax expense	<u>–</u>

(ii) Deferred taxation:

For the purpose of presentation in the consolidated statement of financial position, deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when the deferred taxes relate to the same legal entity and fiscal authority. The following is the analysis of the deferred tax balances for financial reporting purposes:

	As at December 31, 2023
	<i>RMB’000</i>
Deferred tax assets	9,457
Deferred tax liabilities	<u>(9,457)</u>
	<u>–</u>

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The following are the major deferred tax assets/(liabilities) recognised and movements thereon during the Track Record Period:

	<u>Right-of-use assets</u>	<u>Lease liabilities</u>	<u>Total</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount			
As at January 1, 2023	(5,552)	5,552	–
(Charge) credit to profit or loss	<u>(3,905)</u>	<u>3,905</u>	–
As at December 31, 2023	<u><u>(9,457)</u></u>	<u><u>9,457</u></u>	<u><u>–</u></u>

As at December 31, 2023, the Group has unused tax losses of RMB406,009,000 available for offset against future profits and deductible temporary differences of RMB62,273,000. No deferred tax asset has been recognised in respect of the tax losses or temporary differences due to the unpredictability of future profit streams.

The unused tax losses will be carried forward and expire in years as follows:

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
2024	1,438
2025	3,862
2026	24,146
2027	15,042
2028	79,583
2029	18,461
2030	37,785
2031	82,725
2032	<u>142,967</u>
	<u><u>406,009</u></u>

13. DIRECTORS’, SUPERVISORS’ AND CHIEF EXECUTIVE OFFICER’S EMOLUMENTS AND FIVE HIGHEST PAID INDIVIDUALS

Details of the emoluments paid or payable to the individuals who were appointed as directors, supervisors and the chief executive officer of the Company during the Track Record Period are as follows:

(a) Directors and supervisors

	<u>Date of appointment</u>	<u>Director fees</u>	<u>Salaries and other benefits</u>	<u>Discretionary Bonuses (Note (v))</u>	<u>Retirement benefit scheme contributions</u>	<u>Share-based payments (Note (vi))</u>	<u>Total</u>
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
For the year ended December 31, 2023							
<i>Executive director and general manager:</i>							
Dr. Tian Guanghui (Note (vi))	June 28, 2020	–	609	116	46	14,745	15,516
<i>Executive director:</i>							
Dr. Hu Tianwen	June 20, 2023	–	476	204	62	–	742

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	Date of appointment	Director fees	Salaries and other benefits	Discretionary Bonuses (Note (v))	Retirement benefit scheme contributions	Share-based payments (Note (vi))	Total
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
<i>Non-executive directors</i>							
<i>(Note (ii)):</i>							
Dr. Shen (Note (vii))	September 15, 2021	-	-	-	-	-	-
Mr. Liu Haoxuan	June 28, 2020	-	-	-	-	-	-
<i>Independent non-executive directors:</i>							
Dr. Ju Dianwen	March 27, 2023	76	-	-	-	-	76
Ms. Cao Xinwen	March 27, 2023	76	-	-	-	-	76
<i>Supervisors:</i>							
Dr. Yang Rulei	September 15, 2021	-	376	33	38	-	447
Mr. Zhou Hongju (Note (ii))	September 15, 2021	-	-	-	-	-	-
Mr. Li Jian	March 15, 2021	-	398	30	42	-	470
		<u>152</u>	<u>1,859</u>	<u>383</u>	<u>188</u>	<u>14,745</u>	<u>17,327</u>

Notes:

- (i) None of the directors or supervisors of the Company waived or agreed to waive any emoluments during the Track Record Period.
- (ii) The non-executive directors and Mr. Zhou Hongju as the supervisor of the Company, are of the opinion that the service provided to the Group only occupy an insignificant portion of their time and therefore it is concluded that they are not remunerated for such services.
- (iii) During the Track Record Period, no emoluments were paid by the Group to any of the directors or supervisors of the Company as an inducement to join or upon joining the Group or as compensation for loss of office.
- (iv) The executive directors’ and supervisors’ (except for Mr. Zhou Hongju) emoluments shown above were for their services in connection with the management of the affairs of the Group and the Company, respectively.
- (v) The discretionary bonuses were determined with reference to their duties and responsibilities of the relevant individuals within the Group and the Group’s performance.
- (vi) Dr. Tian was granted the restricted shares, in respect of his services to the Group under the restricted shares scheme of the Company. Details of the restricted shares scheme are set out in Note 35 to the Historical Financial Information.
- (vii) Dr. Shen was resigned as non-executive director of the Company in June 2023.
- (viii) Dr. Xu Hongxi was appointed as an independent non-executive director of the Company in January 2025.

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(b) Five highest paid individuals

The five highest paid individuals of the Group included one director of the Company for the year ended December 31, 2023, details of whose remuneration are set out above. Details of the remuneration for the remaining four highest paid individuals for the year ended December 31, 2023 are as follows:

	Year ended December 31, 2023
	<i>RMB’000</i>
Salaries and other benefits	3,803
Retirement benefit scheme contributions	183
Discretionary bonuses (<i>Note</i>)	780
	<u>4,766</u>

Note: Discretionary bonuses were determined based on their duties and responsibilities of the relevant individuals within the Group and the Group’s performance.

The emoluments of the five highest paid individuals for the year ended December 31, 2023 are within the following bands:

	Year ended December 31, 2023
	<i>No. of employees</i>
Hong Kong Dollars (“HK\$”) 1,000,001 to HK\$1,500,000	3
HK\$1,500,001 to HK\$2,000,000	1
HK\$17,000,001 to HK\$17,500,000	1
	<u>5</u>
	=

During the Track Record Period, no emoluments were paid by the Group to the directors of the Company or the five highest paid individuals (including directors and employees) as an inducement to join or upon joining the Group or as compensation for loss of office.

14. EARNINGS PER SHARE

The calculation of the basic earnings per share attributable to the owners of the Company is based on the following data:

Earnings figures are calculated as follows:

	Year ended December 31, 2023
	<i>RMB’000</i>
Earnings	
Earnings for the purpose of basic earnings per share for the year attributable to owners of the Company	<u>12,089</u>
	<i>’000</i>
Number of shares	
Weighted average number of ordinary shares for the purpose of basic earnings per share (<i>Note</i>)	<u>144,558</u>
	<i>RMB</i>
Basic earnings per share	<u>0.08</u>

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Note: The Company was converted to a joint stock company on March 10, 2023, 6,361,242 ordinary shares with par value of RMB1 each were issued and allotted to the respective shareholders of the Company according to the paid-in capital registered under these shareholders on that day. This capitalisation of share capital is applied retrospectively for the purpose of calculating basic earnings per share, as adjusted for the capital contributions by the then shareholders and the number of ordinary shares.

The weighted average number of ordinary shares for the purpose of basic earnings per share has also been adjusted retrospectively for the share conversion on January 13, 2025 as set out in Note 44 to the Historical Financial Information on the assumption that the share conversion had been effective at the beginning of the Track Record Period.

No diluted earnings per share for the year ended December 31, 2023 was presented as there were no potential ordinary shares in issue for the year ended December 31, 2023.

15. DIVIDENDS

No dividend was declared or paid by the Company during the Track Record Period.

16. PROPERTY, PLANT AND EQUIPMENT

The Group

	Buildings	Leasehold improvements	Machinery and equipment	Office equipment and fixtures	Vehicles	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
COST							
As at January 1, 2023	–	–	16,333	2,043	–	229,960	248,336
Additions	48	–	10,047	1,963	81	65,369	77,508
Transfer	–	12,888	26,990	–	–	(39,878)	–
As at December 31, 2023	<u>48</u>	<u>12,888</u>	<u>53,370</u>	<u>4,006</u>	<u>81</u>	<u>255,451</u>	<u>325,844</u>
DEPRECIATION							
As at January 1, 2023	–	–	8,630	1,265	–	–	9,895
Provided for the year	–	1,491	4,670	691	15	–	6,867
As at December 31, 2023	<u>–</u>	<u>1,491</u>	<u>13,300</u>	<u>1,956</u>	<u>15</u>	<u>–</u>	<u>16,762</u>
CARRYING AMOUNT							
As at December 31, 2023	<u>48</u>	<u>11,397</u>	<u>40,070</u>	<u>2,050</u>	<u>66</u>	<u>255,451</u>	<u>309,082</u>

The Company

	Machinery and equipment	Office equipment and fixtures	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
COST				
As at January 1, 2023	16,225	1,706	–	17,931
Additions	656	311	12,071	13,038
As at December 31, 2023	<u>16,881</u>	<u>2,017</u>	<u>12,071</u>	<u>30,969</u>
DEPRECIATION				
As at January 1, 2023	8,630	1,154	–	9,784
Provided for the year	2,040	335	–	2,375
As at December 31, 2023	<u>10,670</u>	<u>1,489</u>	<u>–</u>	<u>12,159</u>
CARRYING AMOUNT				
As at December 31, 2023	<u>6,211</u>	<u>528</u>	<u>12,071</u>	<u>18,810</u>

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The above items of property, plant and equipment, other than construction in progress, are depreciated on a straight-line basis, after taking into account of the residual value, over the following period:

Buildings	20 years
Leasehold improvements	Over the shorter of the relevant lease terms or 5 years
Machinery and equipment	5 or 10 years
Office equipment and fixtures	3 or 5 years
Vehicles	4 years

17. RIGHT-OF-USE ASSETS

The Group

	<u>Leased properties</u>	<u>Land use rights</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Carrying amount			
As at January 1, 2023	22,210	30,832	53,042
Additions	26,687	57,474	84,161
Depreciation charged for the year	<u>(8,355)</u>	<u>(2,571)</u>	<u>(10,926)</u>
As at December 31, 2023	<u>40,542</u>	<u>85,735</u>	<u>126,277</u>

**Year ended
December 31, 2023**

RMB'000

Expenses relating to short-term leases	816
Expenses relating to low-value leases, excluding short-term leases of low-value assets	16
Total cash outflow for leases	<u>57,673</u>

The Company

	<u>Leased properties</u>	<u>Land use right</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Carrying amount			
As at January 1, 2023	–	–	–
Additions	10,163	57,474	67,637
Depreciation charged for the year	<u>(3,379)</u>	<u>(1,916)</u>	<u>(5,295)</u>
As at December 31, 2023	<u>6,784</u>	<u>55,558</u>	<u>62,342</u>

**Year ended
December 31, 2023**

RMB'000

Expenses relating to short-term leases	402
Expenses relating to low-value leases, excluding short-term leases of low-value assets	13
Total cash outflow for leases	<u>50,269</u>

During the Track Record Period, the land use right of the Group and the Company represented the prepaid lease payment for lands located in the PRC with the fixed period of 30 years to 50 years and 30 years, respectively.

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During the Track Record Period, the Group and the Company lease various properties for the operations. The Group’s and the Company’s lease contracts are entered into for fixed term of 3 to 6 years and 3 years, respectively. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. There were no extension options in the lease contracts. In determining the lease term and assessing the length of the non-cancellable period, the Group and the Company apply the definition of a contract and determines the period for which the contract is enforceable.

In addition, the Group and Company own several industrial leasehold lands for construction in progress. Lump sum payments were made upfront to acquire these leasehold lands. The leasehold land components of these owned properties are presented separately since the payments made can be allocated reliably. The lease terms for certain leasehold lands leased by the Group and Company are 30 or 50 years and 30 years respectively.

The Group regularly entered into short-term leases for apartments and motor vehicles. As at December 31, 2023, the portfolio of short-term leases is similar to the portfolio of short-term leases to which the short-term lease expense disclosed above.

Restrictions or covenants on leases

As at December 31, 2023, the Group’s and Company’s lease liabilities of RMB41,502,000 and RMB6,961,000 are recognised with related right-of-use assets of RMB40,542,000 and RMB6,784,000 respectively. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased properties may not be used as security for borrowing purposes.

Sale and leaseback transaction

To better manage the Group’s capital structure and financing needs, the Group sometimes enters into sale and leaseback arrangements in relation to machinery leases. These legal transfers do not satisfy the requirements of IFRS 15 to be accounted for as a sale of the machinery. During the year ended December 31, 2023, the Group has raised RMB20,900,000 borrowings (net of a deposit of RMB1,1000,000 to offset future repayments of the borrowings) in respect of such sale and leaseback arrangement. The Company did not enter such sale and leaseback arrangement for the year ended December 31, 2023.

Details of the lease maturity analysis of lease liabilities are set out in Note 30 to the Historical Financial Information.

18. INTANGIBLE ASSETS

The Group

	Capitalised development costs	In-licenses	Software	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
COST				
As at January 1, 2023	6,214	36,500	–	42,714
Additions	<u>10,194</u>	<u>17,280</u>	<u>408</u>	<u>27,882</u>
As at December 31, 2023	<u>16,408</u>	<u>53,780</u>	<u>408</u>	<u>70,596</u>
AMORTISATION AND IMPAIRMENT				
As at January 1, 2023	–	2,500	–	2,500
Charged for the year	<u>–</u>	<u>–</u>	<u>22</u>	<u>22</u>
As at December 31, 2023	<u>–</u>	<u>2,500</u>	<u>22</u>	<u>2,522</u>
CARRYING AMOUNT				
As at December 31, 2023	<u>16,408</u>	<u>51,280</u>	<u>386</u>	<u>68,074</u>

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The Company

	Capitalised development costs	In-licenses	Software	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
COST				
As at January 1, 2023	6,214	28,500	–	34,714
Additions	9,609	12,340	408	22,357
As at December 31, 2023	<u>15,823</u>	<u>40,840</u>	<u>408</u>	<u>57,071</u>
AMORTISATION AND IMPAIRMENT				
As at January 1, 2023	–	2,500	–	2,500
Charged for the year	–	–	22	22
As at December 31, 2023	<u>–</u>	<u>2,500</u>	<u>22</u>	<u>2,522</u>
CARRYING AMOUNT				
As at December 31, 2023	<u>15,823</u>	<u>38,340</u>	<u>386</u>	<u>54,549</u>

The above intangible assets have finite useful lives. Such intangible assets are amortised on a straight-line basis over the following periods:

Capitalised development costs	Over the residual useful life when ready for use
In-licenses	Over the residual useful life when ready for use
Software	10 years

In-licensing agreements

Historically, the Group entered into several in-licensing agreements with Topharman Shanghai Co., Ltd.* (上海特化醫藥科技有限公司) (“Topharman Shanghai”) and Topharman Shandong Co., Ltd.* (山東特喆曼藥業有限公司) (“Topharman Shandong”) and other independent third parties. Topharman Shanghai and Topharman Shandong are controlled by one of the founders of the Company, Dr. Shen.

Pursuant to these in-licensing agreements, the Group acquired exclusive intellectual property rights related to (i) TPN171, (ii) TPN102, (iii) LV232, (iv) a category of resorcinol compound and its application in neurological disorders, (v) a category of antiviral nucleoside analogs and pharmaceutical compositions and its application, (vi) a category of aromatic amines compound and its application on a global scale; and (vii) 50% of exclusive intellectual property rights related to a category of baicalein derivatives and its application in the world except for five countries in Central Asia (comprising Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, and Turkmenistan) from the counterparties.

In exchange for aforementioned intellectual property rights, the Group obligated to pay the consideration consisting of upfront payment, milestone payments and sales royalties based on certain percentage determined in each in-licensing agreement of annual sales realised in granted areas to the counterparties.

During the year ended December 31, 2023, the Group paid upfront payments and milestone payments of RMB15,530,000, and the Group accrued milestone payable of RMB1,750,000 to Topharman Shanghai for the agreed milestone reached during the year. As at December 31, 2023, the Group had paid upfront payments and milestone payments of RMB51,030,000, and the Group accrued milestone payable of RMB2,750,000 to Topharman Shanghai. Such amounts were capitalised by the Group as intangible assets when the payment obligation became unconditional. As at December 31, 2023, the Company had paid upfront payments and milestone payments of RMB39,840,000, and the Company accrued milestone payable of RMB1,000,000 to Topharman Shanghai. Such amounts were capitalised by the Company as intangible assets when the payment obligation became unconditional.

* English name is for identification purpose only.

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The Company recognised a full impairment loss of RMB2,500,000 for an in-licensing agreement recognised as intangible asset given no economic benefits can be recovered in 2022, since the Company internally determined to cease the research and develop activities in respect of the in-licensing agreement in 2022. Subsequently, the Company signed a termination agreement with counterparties in respect of the in-licensing agreement in June 2024, and the Company no longer has any interests and rights regarding the in-licensing agreement. The related intangible asset was disposed, and the impairment was written-off accordingly.

As at December 31, 2023, the remaining uncompleted milestone payments up to an aggregate amount of RMB312,620,000 and RMB247,560,000 (excluding royalties charged on annual sales) for the Group and the Company respectively, are subject to the future achievement of remaining milestone criteria.

19. IMPAIRMENT TESTING ON INTANGIBLE ASSETS NOT READY FOR USE

Impairment test

In-licenses and capitalised development costs, which are intangible assets not yet ready for use, are tested impairment annually based on the recoverable amount of the cash-generating unit to which the intangible asset is related. The appropriate cash-generating unit is at the pipeline or potential pipeline level.

Impairment test on the in-licenses of the Group has been conducted by the management of the Group by engaging an independent qualified professional valuer, AVISTA Valuation Advisory Limited (“AVISTA”), to estimate the recoverable amount of the cash-generating unit at the end of each year. The address of AVISTA is Suites 2401-06, 24/F, Everbright Centre, No. 108 Gloucester Road, Wan Chai, Hong Kong. Impairment test on the capitalised development costs has been conducted by the management of the Group. For the purpose of impairment test, the recoverable amount of the cash-generating unit is determined by using the discounted cash flow approach.

With the assistance of AVISTA, the management determined the recoverable amount of the above cash-generating units based on the following approach and the key assumptions:

- The cash-generating unit will generate cash inflows starting from certain years (as disclosed in below key parameters) based on the timing of clinical development and regulatory approval for each pipeline, commercial ramp up to reach expected peak revenue potential till certain years (as disclosed in below key parameters), and up to the end of the exclusivity for the product;
- The expected market penetration rate was based on the expected selling conditions considering the features of marketing and technology development;
- The discount rate used is pre-tax and reflect market assessments of time value and the specific risks relating to the industry; and
- The expected success rate of commercialisation by reference to practices of pharmaceutical industries, development of technologies and related regulations from administrations.

The range of key parameters used for recoverable amount calculations of in-licenses are as follows:

	<u>As at December 31, 2023</u>
The year for the commencement of generating cash flow	2024 – 2034
The year achieved peak sales	2037 – 2042
Expected annual growth rates till the year achieved peak sales	2.8% – 631.9%
Expected market penetration rate	0.5% – 28.9%
Pre-tax discount rate	15.1% – 16.3%

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The range of key parameters used for recoverable amount calculations of capitalised development costs are as follows:

	<u>As at December 31, 2023</u>
The year for the commencement of generating cash flow	2024 – 2026
Expected annual growth rates till 2035	10.0% – 49.1%
Expected market penetration rate	0.1% – 19.6%
Pre-tax discount rate	16.3% – 23.5%

The revenue growth rate for the forecast period and budgeted gross margin were determined by the management based on their expectation for market and product development.

Based on the result of impairment test, there was no impairment for the above in-licenses and capitalised development costs as at December 31, 2023. Management believes that any reasonably possible change in any of these assumptions would not result in impairment.

20. INTERESTS IN SUBSIDIARIES

The Company

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
Cost of investments	<u>42,411</u>

21. OTHER NON-CURRENT ASSETS

The Group

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
Value-Added Tax (“VAT”) recoverable	4,449
Long-term deposits	1,738
Prepayments for property, plant and equipment	492
	<u>6,679</u>

The Company

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
VAT recoverable	2,555
Long-term deposits	140
	<u>2,695</u>

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ACCOUNTANTS’ REPORT

22. INVENTORIES

The Group

	As at December 31, 2023
	<i>RMB’000</i>
Raw materials and consumables	3,174
Finished goods	35
	<u>3,209</u>

The Company

	As at December 31, 2023
	<i>RMB’000</i>
Raw materials	182

23. TRADE RECEIVABLES

The Group

	As at December 31, 2023
	<i>RMB’000</i>
Trade receivables	38,773
Less: allowance for credit losses	2,221
	<u>36,552</u>

As at January 1, 2023, trade receivables from contracts with customers of the Group amounted to RMB7,155,000.

The Company

	As at December 31, 2023
	<i>RMB’000</i>
Trade receivables from third parties	38,773
Trade receivables from subsidiaries (<i>Note 36(i)</i>)	14,532
	<u>53,305</u>
Less: allowance for credit losses	2,221
	<u>51,084</u>

As at January 1, 2023, trade receivables from contracts with customers of the Company amounted to RMB21,057,000.

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The following is an aged analysis of trade receivable net of allowance for credit losses presented based on invoice date as at December 31, 2023:

The Group

	As at December 31, 2023
	<i>RMB’000</i>
1 to 30 days	16,174
31 to 60 days	20,000
121 to 180 days	45
Over 360 days	333
	<u>36,552</u>

The Company

	As at December 31, 2023
	<i>RMB’000</i>
1 to 30 days	23,028
31 to 60 days	20,000
121 to 180 days	7,723
Over 360 days	333
	<u>51,084</u>

For the third parties, the Group and the Company normally grants a credit period of 30 to 60 days or a particular period agreed with third party customers effective from the date when the services have been completed or control of goods has been transferred to the customer and billed to the customer. The Company does not have a credit period term to its subsidiaries. For certain trade receivables balances which have been past due more than 90 days, the directors of the Company consider they are not in default since such balances could be recovered based on the historical repayment pattern of overdue trade receivables and the financial conditions of corresponding customers.

Details of impairment assessment of trade receivables are set out in Note 39(b) to the Historical Financial Information.

24. PREPAYMENTS AND OTHER RECEIVABLES

The Group

	As at December 31, 2023
	<i>RMB’000</i>
Prepayments for purchase of materials and research and development services	4,117
Other receivables	2,263
Less: allowance for credit losses	113
	<u>2,150</u>
Deposits	242
Prepayments for short-term rental and property management fee	130
	<u>6,639</u>

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The Company

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
Prepayments for purchase of materials and research and development services	3,151
Other receivables	2,260
Less: allowance for credit losses	<u>113</u>
	2,147
Deposits	<u>95</u>
	<u>5,393</u>

25. CONTRACT ASSETS

The Group and the Company

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
<u>CRO services</u>	
Contract assets	3,383
Less: allowance for credit losses	<u>969</u>
	<u>2,414</u>

As at 1 January 2023, contract assets of the Group and the Company amounted to RMB1,301,000 and RMB1,301,000, respectively.

The contract assets primarily relate to the Group’s and Company’s right to consideration for work completed in connection to CRO services and not billed because the rights are conditioned on the Group’s future performance. The contract assets are transferred to trade receivables when the rights become unconditional.

Typical payment terms which impact on the amount of contract assets recognised are as follows:

The contract assets represent the Group’s and the Company’s rights to consideration for the services performed to date. Payment for CRO services is not due from the customer until the milestone criteria determined in the CRO contracts with the customers are met and therefore a contract asset is recognised over the period in which the CRO services are performed.

The Group and the Company classify these contract assets as current because the Group and the Company expect to realise them in its normal operating cycle.

Details of impairment assessment of contract assets are set out in Note 39(b) to the Historical Financial Information.

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ACCOUNTANTS’ REPORT

26. OTHER CURRENT ASSETS

The Group

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
VAT recoverable	21,396

The Company

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
VAT recoverable	1,198

27. BANK BALANCES AND CASH

The Group

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Bank balances	95,942
Cash on hand	32
	<u>95,974</u>

The carrying amounts of the Group’s bank balances and cash denominated in currencies other than functional currencies of the relevant group entities at the end of each reporting period are as follows:

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
United States Dollars (“US\$”)	2,282

The Company

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Bank balances	81,664
Cash on hand	32
	<u>81,696</u>

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Bank balances and cash denominated in currencies other than functional currency of the Company at the end of each reporting period are as follows:

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
US\$	94
	<u> </u>

Bank balances held by the Group and the Company carry interests at market rates ranging from 0.25% to 2.00% as at December 31, 2023, respectively.

28. TRADE AND OTHER PAYABLES

The Group

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Trade payables for research and development expenses	615
Accrued research and development expenses	19,710
Payables for construction in progress	85,884
Accrued staff costs and benefits	9,549
Payables in respect of acquisition of intangible assets	2,750
Payables for machineries and equipment	2,406
Other tax payables	1,590
Deposits	672
	<u>123,176</u>
	<u> </u>

The Company

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Trade payables for research and development expenses	136
Accrued research and development expenses	20,840
Payables for construction in progress	9,782
Accrued staff costs and benefits	7,835
Payables in respect of acquisition of intangible assets	1,000
Other tax payables	2,017
Payables for machineries and equipment	18
Deposits	12
	<u>41,640</u>
	<u> </u>

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ACCOUNTANTS’ REPORT

The following is an aged analysis of trade payables presented based on the invoice dates at the end of each reporting period:

The Group

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Within 30 days	256
31-90 days	16
91-180 days	46
181-365 days	153
Over 365 days	<u>144</u>
	<u>615</u>

The Company

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Within 30 days	4
Over 365 days	<u>132</u>
	<u>136</u>

The average credit period granted by suppliers is normally 30 to 60 days. There is no credit period terms for the balances between the Company and its subsidiaries.

29. CONTRACT LIABILITIES

The Group

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
CRO services	<u>6,961</u>

As at 1 January 2023, contract liabilities of the Group amounted to RMB9,154,000.

The Company

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
CRO services	<u>7,079</u>

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As at 1 January 2023, contract liabilities of the Company amounted to RMB9,154,000.

Typical payment terms which impact on the amount of contract liabilities recognised are as follows:

When the amount of milestone payment according to the payment schedule determined in the CRO service contract received by the Group exceeds the amount of the revenue could be recognised based on the proportion of completion of the CRO service rendered to date, this will give rise to contract liabilities. The stage milestone results in contract liabilities being carried forward to recognise as revenue when the performance obligation of corresponding CRO service is satisfied.

The Group and the Company classify these contract liabilities as current because the Group and the Company expect to realise them in its normal operating cycle.

30. LEASE LIABILITIES

The Group

	As at December 31, 2023
	<i>RMB'000</i>
Lease liabilities payable:	
Within one year	10,860
Within a period of more than one year but not exceeding two years	9,079
Within a period of more than two years but not exceeding five years	20,128
More than five years	1,435
	<u>41,502</u>
Less: Amount due for settlement within 12 months shown as current liabilities	10,860
Amount due for settlement after 12 months shown as non-current liabilities	<u>30,642</u>

The Company

	As at December 31, 2023
	<i>RMB'000</i>
Lease liabilities payable:	
Within one year	4,334
Within a period of more than one year but not exceeding two years	2,627
	<u>6,961</u>
Less: Amount due for settlement within 12 months shown as current liabilities	4,334
Amount due for settlement after 12 months shown as non-current liabilities	<u>2,627</u>

The weighted average incremental borrowing rates applied to the lease liabilities is 3.45% to 4.30% per annum for the Track Record Period.

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31. BORROWINGS

The Group

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
<u>At amortised cost</u>	
Bank loans	263,614
Other loan in respect of sale and leaseback arrangement (<i>Note 17</i>)	15,912
	<u>279,526</u>
Secured	126,911
Unsecured	152,615
	<u>279,526</u>

Secured bank loans are pledged by land use rights and the construction in progress on the corresponding land use rights owned by the Group amounted to RMB85,735,000 and RMB255,451,000 respectively as at December 31, 2023. In addition, the secured bank loan of a subsidiary of the Group is guaranteed by the Company.

The carrying amounts of the above borrowings are analysed based on contractual repayment date as follows:

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
The carrying amounts of the above borrowings are repayable:	
Within one year	133,751
Within a period of more than one year but not exceeding two years	74,706
Within a period of more than two years but not exceeding five years	71,069
	<u>279,526</u>
Less: Amount due within one year shown under current liabilities	133,751
Amount shown under non-current liabilities	<u>145,775</u>

The Company

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
<u>At amortised cost</u>	
Bank loans	139,451
Secured	999
Unsecured	138,452
	<u>139,451</u>

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The secured bank loan is pledged by a land use right and the construction in progress on the land use right owned by the Company amounted to RMB55,558,000 and RMB12,071,000 respectively as at December 31, 2023.

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
The carrying amounts of the above borrowings are repayable:	
Within one year	99,252
Within a period of more than one year but not exceeding two years	39,200
Within a period of more than two years but not exceeding five years	<u>999</u>
	139,451
Less: Amount due within one year shown under current liabilities	<u>99,252</u>
Amount shown under non-current liabilities	<u><u>40,199</u></u>

The exposure of the Group’s and Company’s borrowings are as follows:

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
The Group	
Fixed-rate borrowings	97,735
Variable-rate borrowings	181,791
The Company	
Fixed-rate borrowings	88,572
Variable-rate borrowings	50,879

The Group’s variable-rate borrowings carry interest at LPR. Interest rates are reset every year.

The ranges of effective interest rates (which are also equal to contracted interest rates) on the Group’s and Company’s borrowings are as follows:

	<u>Year ended December 31, 2023</u>
Effective interest rate:	
The Group	
Fixed-rate borrowings	3.75% to 4.15%
Variable-rate borrowings	3.50% to 5.50%
The Company	
Fixed-rate borrowings	3.75% to 4.15%
Variable-rate borrowings	3.50% to 4.00%

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32. DEFERRED INCOME

The Group

	As at December 31, 2023
	<i>RMB’000</i>
Government grants related to property, plant and equipment (<i>Note (i)</i>)	13,233
Other subsidy (<i>Note (ii)</i>)	<u>12,900</u>
	26,133
Less: Amount due within one year shown under current liabilities	179
Amount shown under non-current liabilities	<u><u>25,954</u></u>

The Company

	As at December 31, 2023
	<i>RMB’000</i>
Other subsidy (<i>Note (ii)</i>)	<u>12,900</u>

Notes:

- (i) The Group received government grants for capital expenditure incurred for the purpose of compensation for construction in progress of the Group.
- (ii) Other subsidy is provided in relation to the research and development activities of the Company.

Deferred income of the Company are all classified as non-current liabilities as at December 31, 2023.

33. SHARE CAPITAL AND PAID-IN CAPITAL

As disclosed in Note 1, the Company converted into a joint stock company on March 10, 2023, the balance as at January 1, 2023 represented the paid-in capital of the Company prior to the conversion of the Company. Share capital as at December 31, 2023 represented the issued share capital of the Company.

Paid-in capital

	Paid-in capital
	<i>RMB’000</i>
Issued and paid	
As at January 1, 2023	6,361
Conversion into a joint stock company (<i>Note</i>)	<u>(6,361)</u>
As at December 31, 2023	<u><u>–</u></u>

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Share capital

	Number of shares	Nominal value of shares <i>RMB'000</i>
Ordinary shares of RMB1 each		
Authorised and issued		
As at January 1, 2023	–	–
Conversion into a joint stock company (<i>Note</i>)	<u>6,361,242</u>	<u>6,361</u>
As at December 31, 2023	<u>6,361,242</u>	<u>6,361</u>

Note: On March 10, 2023, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC. The net assets of the Company as of the conversion date of November 30, 2022, including paid-in capital, reserves and accumulated losses, amounting to approximately RMB183,062,000 were converted into 6,361,242 shares with a nominal value of RMB1.00 each. The excess of net assets converted over nominal value of the ordinary shares was credited to the Company’s share premium.

34. RESERVES OF THE COMPANY

	Capital reserve	Share premium	Share-based payment reserve	(Accumulated losses) retained earnings	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
As at January 1, 2023	348,639	–	63,320	(226,157)	185,802
Profit for the year	–	–	–	50,822	50,822
Conversion into a joint stock company (<i>Note 33</i>)	(348,639)	176,701	(62,092)	234,030	–
Recognition of equity-settled share-based payments (<i>Note 35</i>)	–	–	14,745	–	14,745
As at December 31, 2023	<u>–</u>	<u>176,701</u>	<u>15,973</u>	<u>58,695</u>	<u>251,369</u>

35. SHARE-BASED PAYMENT TRANSACTIONS

Restricted share scheme

In recognition of the contributions of certain eligible directors and employees, Dr. Shen, one of the founders of the Company established an employee stock ownership platform, namely Suzhou Nanbowan Enterprise Management Consulting Partnership (Limited Partnership)* (蘇州南博萬企業管理諮詢合夥企業(有限合夥)) (“Suzhou Nanbowan”) in November 2018, to hold the Company’s paid-in capital of RMB750,000, which was transferred from the founder, to implement restricted shares (“RS”) scheme (“Suzhou Nanbowan RS Scheme”). Under the Suzhou Nanbowan RS Scheme, eligible directors and employees shall subscribe for partnership interests of Suzhou Nanbowan at a consideration price of RMB1 for each RMB1 registered capital and indirectly hold the incentive shares of the Company.

Pursuant to Suzhou Nanbowan RS Scheme, the RSs granted shall be vested on the fourth anniversary date of the grant date. If the grantees terminate their labor relationships with the Group within the vesting period, the executive partner of Suzhou Nanbowan who is one of the founders of the Company, or a third party designated by the executive partner shall buy back the unvested RSs at original consideration plus interests at 10% per annum.

* English name is for identification purpose only.

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Details of the unvested restricted shares as at December 31, 2023 under the Suzhou Nanbowan RS Scheme are as follows:

Grant date	Amount of registered capital	Grantee
	<i>RMB'000</i>	
June 28, 2021	350	A director

The Company was converted to a joint stock company on March 10, 2023, 6,361,242 ordinary shares with par value of RMB1 each were issued and allotted to the respective shareholders of the Company according to the paid-in capital registered under these shareholders on that day and following table to reflect the impact of the conversion. 1 registered capital before the conversion represented 1 share of the joint stock company:

	Unvested registered capital	Weighted average grant date fair value per registered capital
	<i>'000</i>	<i>RMB</i>
Unvested as at January 1, 2023 and December 31, 2023	<u>350</u>	<u>168.54</u>

Fair value of RSs granted

Back-solve method was used to determine the underlying equity fair value of the Company and equity allocation method was used to determine the fair value of the RSs granted. The fair value of shares at grant date was valued by directors of the Company with reference to valuation reports carried out by an independent qualified professional valuer, AVISTA, whose address is disclosed in Note 19 to the Historical Financial Information. The fair value of RSs at grant date was determined by taking into account of the fair value of the equity of the Company amounting to RMB169.54 per share and the purchase price of the RS is RMB1 per share. The inputs into the model were as follows:

	June 28, 2021
Expected volatility	46.87%
Risk-free rate	2.57%
Expected dividend yield	<u>0%</u>

The Group has recognised share-based payment expenses of RMB14,745,000 for the year ended December 31, 2023.

36. RELATED PARTY TRANSACTIONS

- (i) Other than as disclosed elsewhere in the Historical Financial Information, the Group has the following transactions with its fellow subsidiaries under the common control of the founder of the Company during the Track Record Period.

Purchase of pharmaceutical ingredient with ancillary service from related parties

	Year ended December 31, 2023
	<i>RMB'000</i>
Topharman Shandong	<u>10,010</u>
<u>Purchase of in-licenses from related parties</u>	
Topharman Shanghai	<u>1,750</u>

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Interests on loan from a related party

	<u>Year ended December 31, 2023</u>
	<i>RMB’000</i>
Topharman Shanghai	385
(ii) Other than as disclosed elsewhere in the Historical Financial Information, as at the end of the Track Record Period, the Group and the Company had balances with related parties as follows, which are all unsecured, as follows:	

The Group

Trade payables

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
Topharman Shandong	6,097
Topharman Shanghai	2,750
	<u>8,847</u>

Amounts due to a related party

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
Topharman Shanghai (<i>Note</i>)	<u>10,882</u>

Note: The amounts due to Topharman Shanghai are loans from Topharman Shanghai to Nantong Hefeng Lianwang Pharmaceutical Technology Co., Ltd.* (南通和風連旺醫藥科技有限公司) (“Vigonvita Nantong”), a non-wholly owned subsidiary of the Company, with a fixed interest rate of 3.85%. The principal of RMB10,000,000 and corresponding interests are fully repayable in 2024. Therefore, the amounts due to Topharman Shanghai were classified as current liabilities in the consolidated statement of financial position as at December 31, 2023. In 2024, the Company signed the supplementary agreements with Topharman Shanghai to extend the final repayment date to September 30, 2025. The Group expects to settle the amount due to a related party before of the [REDACTED] of H Shares of the Company on the Stock Exchange.

The Company

Trade receivables

	<u>As at December 31, 2023</u>
	<i>RMB’000</i>
旺山旺水(連雲港)製藥有限公司	
Vigonvita (Lianyungang) pharmaceutical Co., Ltd.*	
(“Vigonvita Lianyungang”)	13,579
Vigonvita Nantong	953
	<u>14,532</u>

No ECL allowance was recognised for the above trade receivables as at December 31, 2023.

* English name is for identification purpose only.

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Amounts due from subsidiaries

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Vigonvita Lianyungang	103,389
旺山旺水(上海)生物醫藥有限公司	
Vigonvita (Shanghai) Life Sciences Co., Ltd.* (“Vigonvita Shanghai”)	36,098
Vigonvita Nantong	3,500
	<u>142,987</u>

No ECL allowance was recognised for the above amounts due from subsidiaries as at December 31, 2023.

The amounts due from subsidiaries were non-trade in nature, interest free, unsecured and repayable on demand. The Company does not expect to realise the above amounts due from subsidiaries within twelve months after December 31, 2023, therefore, such balances are classified as non-current assets.

Trade payables

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Topharman Shanghai	1,000
Vigonvita Lianyungang	1,367
	<u>2,367</u>

Contract liabilities

	<u>As at December 31, 2023</u>
	<i>RMB'000</i>
Vigonvita Lianyungang	118

Compensation of key management personnel

The remuneration of directors and supervisors of the Company and other members of key management was as follows:

	<u>Year ended December 31, 2023</u>
	<i>RMB'000</i>
Salaries and other benefits	4,862
Retirement benefits scheme contribution	371
Discretionary bonus (<i>Note</i>)	841
Share-based payments	14,745
	<u>20,819</u>

Note: Discretionary bonus is determined based on their duties and responsibilities of the relevant individuals within the Group and the Group’s performance.

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37. CAPITAL COMMITMENTS

The Group

	As at December 31, 2023
	<i>RMB’000</i>
Capital expenditure contracted for but not provided in the Historical Financial Information in respect of:	
– acquisition of property, plant and equipment	100,286

The Company

	As at December 31, 2023
	<i>RMB’000</i>
Capital expenditure contracted for but not provided in the Historical Financial Information in respect of:	
– acquisition of property, plant and equipment	24,916

38. CAPITAL RISK MANAGEMENT

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximising the return to investors through the optimisation of the debt and equity balance. The Group’s overall strategy remains unchanged throughout the Track Record Period.

The capital structure of the Group consists of net debts, which includes amounts due to a related party disclosed in Note 36(ii), lease liabilities disclosed in Note 30 and borrowings disclosed in Note 31, net of bank balances and cash disclosed in Note 27 and equity attributable to owners of the Company, comprising paid-in capital, share capital and reserves.

The management of the Group reviews the capital structure regularly. As part of this review, the management of the Group considers the cost of capital. Based on recommendation of the management of the Group, the Group will balance its overall capital structure through the new share issues or issue of new debt.

39. FINANCIAL INSTRUMENTS

(a) Categories of financial instruments

The Group

	As at December 31, 2023
	<i>RMB’000</i>
<u>Financial assets</u>	
Amortised cost	136,656
<u>Financial liabilities</u>	
Amortised cost	382,735
Lease liabilities	41,502

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The Company

	As at December 31, 2023
	<i>RMB’000</i>
<u>Financial assets</u>	
Amortised cost	278,149
<u>Financial liabilities</u>	
Amortised cost	150,399
Lease liabilities	6,961

(b) Financial risk management objectives and policies

The Group’s major financial instruments include trade receivables, other receivables, bank balances and cash, trade and other payables, amounts due to a related party, lease liabilities and borrowings. The Company’s major financial instruments include trade receivables, other receivables, amounts due from subsidiaries, bank balances and cash, trade and other payables, lease liabilities and borrowings. Details of these financial assets and liabilities are disclosed in respective notes.

The risks associated with the financial instruments include market risk (currency risk and interest rate risk), credit risk and liquidity risk. The policies on how to mitigate these risks are set out below. The management manages and monitors these exposures to ensure appropriate measures are implemented on a timely and effective manner.

Market risk

The Group’s and the Company’s activities expose it primarily to currency risk and interest rate risk. There has been no change in the Group’s and the Company’s exposure to these risks or the manner in which it manages and measures the risks.

(i) Currency risk

Certain financial assets and liabilities are denominated in foreign currencies of respective group entities which are exposed to foreign currency risk. The Group currently does not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

The carrying amounts of the Group’s and the Company’s foreign currencies denominated monetary assets and liabilities at the end of the Track Record Period are as follows:

The Group

	As at December 31, 2023
	<i>RMB’000</i>
Assets	
US\$	2,623

The Company

	As at December 31, 2023
	<i>RMB’000</i>
Assets	
US\$	435

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Sensitivity analysis

The following table details the Group’s sensitivity to a 5% increase and decrease in RMB against US\$, the foreign currencies with which the Group may have a material exposure. 5% represents management’s assessment of the reasonably possible change in foreign exchange rates. The sensitivity analysis uses outstanding foreign currencies denominated monetary items as a base and adjusts their translation at the end of each reporting period for a 5% change in foreign currency rates. A negative number below indicates a decrease in profit where RMB strengthens 5% against US\$. For a 5% weakening of RMB against US\$, there would be an equal and opposite impact on the profit for the year.

	<u>Year ended</u> <u>December 31, 2023</u>
	<i>RMB’000</i>
Profit or loss	<u>(131)</u>

(ii) *Interest rate risk*

The Group and the Company are primarily exposed to fair value interest rate risk in relation to lease liabilities (Note 30) and fixed-rate borrowings (Note 31) and cash flow interest rate risk in relation to bank balances (Note 27) and variable-rate borrowings (Note 31). The Group currently does not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

Sensitivity analysis

The sensitivity analyses below have been determined based on the exposure to interest rates at the end of the Track Record Period. The analysis is prepared assuming the financial instruments outstanding at the end of Track Record Period were outstanding for the whole year. A 50 basis point increase or decrease in variable-rate bank borrowings are used which represents management’s assessment of the reasonably possible change in interest rates. Bank balances are excluded from sensitivity analysis as the management considers that the exposure of cash flow interest rate risk arising from variable-rate bank balances is insignificant.

If interest rates had been 50 basis points higher/lower and all other variables were held constant, the Group’s post-tax profit for the year ended December 31, 2023 would decrease/increase by RMB650,000. This is mainly attributable to the Group’s and the Company’s exposure to interest rates on its variable-rate bank borrowings.

Credit risk and impairment assessment

Credit risk refers to the risk that the Group’s and the Company’s counterparties default on their contractual obligations resulting in financial losses to the Group and the Company. The Group’s and the Company’s credit risk exposures are primarily attributable to trade receivables, other receivables, contract assets, amounts due from subsidiaries and bank balances. The Group does not hold any collateral or other credit enhancements to cover its credit risks associated with its financial assets.

Trade receivables and contract assets arising from contracts with customers

In order to minimise the credit risk, the management of the Group has delegated a team responsible for determination of credit limits, credit approvals and other monitoring procedures to ensure that follow-up action is taken to recover overdue debts. In this regard, the management of the Group consider that the Group’s credit risk is significantly reduced.

The Group’s and Company’s concentration of credit risk for 84% and 61% of the total trade receivables was due from the Group’s out-licensing and CRO service income for two customers as at December 31, 2023, respectively.

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The Group and the Company perform impairment assessment under ECL model on trade receivable and contract assets balances individually and collectively. Except for items that are subject to individual evaluation, which are assessed for impairment individually, the remaining trade receivables and contract assets balances are assessed collectively, based on the past default experience of the debtor, general economic conditions of the industry in which the debtors operate and an assessment of both the current as well as the forward-looking information that is available without undue cost or effort at the end of the reporting period.

Other receivables and long-term deposits

For other receivables, the management makes periodic individual assessment on the recoverability of other receivables based on historical settlement records, past experience, and also quantitative and qualitative information that is reasonable and supportive forward-looking information. The management believes that there are no significant increase in credit risk of these amounts since initial recognition and the Group provided impairment based on 12m ECL.

Amounts due from subsidiaries

For amounts due from subsidiaries, the Company has applied 12m ECL to measure the loss allowance. The ECL on amounts due from subsidiaries are assessed individually based on the probability of defaults of amounts due from subsidiaries, the management has taken into account the financial position of the counterparties as well as forward looking information that is available without undue cost or effort.

Bank balances

The credit risk on bank balances and pledged bank deposits is limited because the counterparties are banks with high credit ratings assigned by international credit-rating agencies.

The Group’s internal credit risk grading assessment comprises the following categories:

<u>Internal credit rating</u>	<u>Description</u>	<u>Trade receivables/ contract assets</u>	<u>Other financial assets</u>
Low risk	The counterparty has a low risk of default and does not have any past-due amounts	Lifetime ECL – not credit-impaired	12m ECL
Watch list	Debtor frequently repays after due dates but usually settle in full	Lifetime ECL – not credit-impaired	12m ECL
Doubtful	There have been significant increases in credit risk since initial recognition through information developed internally or external resources	Lifetime ECL – not credit-impaired	Lifetime ECL – not credit-impaired
Loss	There is evidence indicating the asset is credit-impaired	Lifetime ECL – credit-impaired	Lifetime ECL – credit-impaired
Write-off	There is evidence indicating that the debtor is in severe financial difficulty and the Group has no realistic prospect of recovery	Amount is written off	Amount is written off

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The tables below detail the credit risk exposures of the Group’s and the Company’s financial assets, which are subject to ECL assessment:

	Notes	Internal credit rating	12m or lifetime ECL	The Group	The Company
				As at December 31, 2023	As at December 31, 2023
				Gross carrying amount	Gross carrying amount
				RMB’000	RMB’000
Financial assets at amortised cost					
Trade receivables	23	Low risk	Lifetime ECL-not credit-impaired	34,388	48,920
		Doubtful	Lifetime ECL-not credit-impaired	4,385	4,385
Other receivables and deposits	24	Low risk	12m ECL	2,505	2,355
Long-term deposits	21	Low risk	12m ECL	1,738	140
Contact assets	25	Low risk	Lifetime ECL-not credit-impaired	1,497	1,497
		Doubtful	Lifetime ECL-not credit-impaired	1,886	1,886
Amounts due from subsidiaries	36(ii)	Low risk	12m ECL	N/A	142,987
Bank balances	27	N/A	12m ECL	95,942	81,664

As part of the Group’s credit risk management, the Group and the Company uses internal credit ratings to assess the impairment for its customers in relation to its operation of out-licensing income, CRO service income and sales of pharmaceutical products.

Debtors with significant outstanding balances and with different credit risk characteristics with gross carrying amounts of trade receivables of RMB36,956,000 as at December 31, 2023 were assessed individually by the Group and Company. Debtors with different credit risk characteristics with gross carrying amounts of contract assets of RMB1,886,000 as at December 31, 2023 were assessed individually by the Group and the Company. The trade receivables from subsidiaries of RMB14,532,000 as at December 31, 2023 were assessed individually by the Company. The remaining trade receivables and contract assets were assessed collectively.

As at December 31, 2023, the credit loss rate of trade receivable and contract assets collectively assessed by the Group and the Company is 1.60% and 1.73%, respectively.

The estimated loss rates are estimated based on historical observed default rates over the expected life of the debtors and are adjusted for forward-looking information that is available without undue cost or effort. The grouping is regularly reviewed by management to ensure relevant information about specific debtors is updated.

As at December 31, 2023, the Group and the Company provided RMB29,000 and RMB29,000 impairment allowance for trade receivables based on collective assessment, respectively. Impairment allowance of RMB2,192,000 and RMB2,192,000 were made on trade receivables with different credit risk characteristics assessed individually by the Group and the Company, respectively.

As at December 31, 2023, the Group and the Company provided RMB26,000 and RMB26,000 impairment allowance for contract assets based on collective assessment, respectively. Impairment allowance of RMB943,000 and RMB943,000 were made on contract assets with different credit risk characteristics assessed individually by the Group and the Company, respectively.

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The following table shows the movement in lifetime ECL that has been recognised for trade receivables and contract assets under the simplified approach.

The Group and the Company

	Lifetime ECL-not credit-impaired
	<i>RMB'000</i>
As at January 1, 2023	607
– Impairment losses recognised	2,742
– Impairment losses reversed	(159)
As at December 31, 2023	<u>3,190</u>

Liquidity risk

In the management of the liquidity risk, the Group and the Company monitors and maintains a level of cash and cash equivalents deemed adequate by the management to finance the Group’s and the Company’s operations and mitigate the effects of fluctuations in cash flows. The Group monitors the utilisations of bank borrowings and relies on issuance of ordinary shares and utilisations of bank facilities as significant sources of liquidity.

As at December 31, 2023, the Group’s net current liabilities were RMB119,625,000, the Company had completed a new round of financing and received total proceeds of RMB160,000,000 during the year ended 2024 as set out in Note 44 to the Historical Financial Information, and the Group had available unutilised bank facilities for expenditure on construction in progress in Suzhou of RMB349,000,000 as at December 31, 2023, the directors of the Company believes that use of proceeds of financing and unutilised facilities could mitigate the liquidity risk of the Group.

The following table details the Group’s and the Company’s remaining contractual maturity for its financial liabilities and lease liabilities based on agreed repayment terms. The table has been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Group can be required to pay. The table includes both interest and principal cash flows.

	Weighted Average effective interest rate	Within 1 year and on demand	1 to 2 years	2 to 5 years	Over 5 years	Total	Carrying amount
	<i>%</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
The Group							
<u>As at December 31,</u>							
<u>2023</u>							
Trade and other payables	–	92,327	–	–	–	92,327	92,327
Borrowings	4.50	129,640	79,264	73,767	–	282,671	279,526
Lease liabilities	4.18	12,356	10,194	21,501	1,456	45,507	41,502
Amounts due to a related party	3.85	11,122	–	–	–	11,122	10,882
		<u>245,445</u>	<u>89,458</u>	<u>95,268</u>	<u>1,456</u>	<u>431,627</u>	<u>424,237</u>

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ACCOUNTANTS’ REPORT

	Weighted Average effective interest rate	Within 1 year and on demand	1 to 2 years	2 to 5 years	Over 5 years	Total	Carrying amount
	%	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
The Company							
As at December 31, 2023							
Trade and other payables	–	10,948	–	–	–	10,948	10,948
Borrowings	3.77	102,070	40,151	1,017	–	143,238	139,451
Lease liabilities	3.65	4,505	2,674	–	–	7,179	6,961
		<u>117,523</u>	<u>42,825</u>	<u>1,017</u>	–	<u>161,365</u>	<u>157,360</u>

(c) Fair value measurements of financial instruments

Fair value of financial assets and financial liabilities that are not measured at fair value on a recurring basis (but fair value disclosures are required)

The directors of the Company consider that the carrying amount of the Group’s and the Company’s financial assets and financial liabilities recorded at amortised cost in the Historical Financial Information approximate their fair values.

40. RETIREMENT BENEFIT PLANS

The employees of the Group in the PRC are members of the state-sponsored retirement benefit scheme organised by the relevant local government authority in the PRC. The PRC entities are required to contribute, based on a certain percentage of the payroll costs of their employees, to the retirement benefit scheme and have no further obligations for the actual payment of pensions or post-retirement benefits beyond the annual contributions. The total amount provided by the Group to the scheme in the PRC and charged to profit or loss are RMB6,472,000 for the year ended December 31, 2023.

41. PARTICULARS OF SUBSIDIARIES

During the Track Record Period and as at the date of this report, the Company has direct equity interests in the following subsidiaries:

Name of subsidiaries	Place/country and date of establishment/ incorporation	Paid-in capital/registered capital	Equity interest attributable to the Company		Principal activities
			As at December 31, 2023	As at the date of this report	
旺山旺水(連雲港)製藥 有限公司 Vigonvita (Lianyungang) pharmaceutical Co., Ltd.* (Note i)	The PRC/ December 6, 2019	RMB30,000,00/ RMB100,000,000	80%	[100%]	Production and commercialisation of innovative drugs
南通和風連旺醫藥科技 有限公司 Nantong Hefeng Lianwang Pharmaceutical Technology Co., Ltd.*	The PRC/ October 10, 2020	RMB10,204,082/ RMB10,204,082	51%	[51%]	Research, development, production and commercialisation of innovative drugs

* English name is for identification purpose only.

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ACCOUNTANTS’ REPORT

Name of subsidiaries	Place/country and date of establishment/ incorporation	Paid-in capital/registered capital	Equity interest attributable to the Company		Principal activities
			As at December 31, 2023	As at the date of this report	
Vigonvita Tashkent	Uzbekistan/ May 12, 2021	UZS5,280,000,000/ UZS5,280,000,000	100%	[100%]	Sales of pharmaceutical drugs
旺山旺水(上海)生物醫藥有限公司 Vigonvita (Shanghai) Life Sciences Co., Ltd.*	The PRC/ August 19, 2022	RMB10,000,000/ RMB10,000,000	100%	[100%]	Research, development of innovative drugs
英久健康諮詢(蘇州)有限公司 Yingjiu Health Consulting (Suzhou) Co., Ltd.*	The PRC/ December 6, 2023	RMB1,000,000/ RMB1,000,000	100%	[100%]	Sales and marketing management
青島安泰如山生物醫藥有限公司 Qingdao Antairushan Life Sciences Co., Ltd.* (“Vigonvita Qingdao”) (Note ii)	The PRC/ April 28, 2024	RMB10,000,000/ RMB50,000,000	N/A	[90%]	Production and commercialisation of innovative drugs

Notes:

- (i) On November 1, 2024, the Company signed an agreement with the non-controlling shareholder of Vigonvita Lianyungang to acquire the remaining 20% equity interest in Vigonvita Lianyungang from its non-controlling shareholder at a cash consideration of RMB8,500,000. [As at the date of this report, the Company owns the entire equity interest in Vigonvita Lianyungang.]
- (ii) Vigonvita Qingdao was wholly invested by the Company and incorporated in April 2024. On June 26, 2024, the Company signed an agreement with an independent third party to transfer 10% equity interest in Vigonvita Qingdao to the independent third party at a cash consideration of RMB100,000 representing 10% of the paid-in capital of Vigonvita Qingdao as at May 31, 2024. [As at the date of this report, the Company owns 90% equity interest in Vigonvita Qingdao.]
- (iii) No statutory financial statements have been prepared for all of the subsidiaries for the year ended December 31, 2023 as there are no statutory audit requirements.

* English name is for identification purpose only.

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ACCOUNTANTS’ REPORT

42. RECONCILIATION OF LIABILITIES ARISING FROM FINANCING ACTIVITIES

The table below details changes in the Group’s liabilities arising from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are those for which cash flows were, or future cash flows will be, classified in the Group’s consolidated statement of cash flows as cash flows from financing activities.

	Lease liabilities	Borrowings	Amount due to a related party	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at January 1, 2023	23,807	181,878	10,497	216,182
Financing cash flow	(10,351)	86,852	–	76,501
Non-cash changes:				
Finance costs	1,405	5,410	385	7,200
Interests capitalised in the cost of construction in progress	–	5,386	–	5,386
New leases entered	26,641	–	–	26,641
As at December 31, 2023	<u>41,502</u>	<u>279,526</u>	<u>10,882</u>	<u>331,910</u>

43. MAJOR NON-CASH TRANSACTIONS

During the Track Record Period, the Group entered into new lease agreements for office premises for 3 to 6 years. On the lease commencement, the Group recognised right-of-use assets amounted to RMB26,641,000 and lease liabilities amounted to RMB26,641,000 during the year ended December 31, 2023, respectively.

44. SUBSEQUENT EVENTS

From April 2024 to September 2024, the Company entered into share subscription agreements with several independent investors and a relative investor, pursuant to which the investors made an aggregate investment of RMB160,000,000 in the Company as consideration for the subscription of 239,482 new ordinary shares issued by the Company. By the end of 2024, the Company had received the total proceeds of RMB160,000,000 for subscription of the new shares.

On January 13, 2025, the Company passed a shareholders’ resolution to (i) increase the share capital of the Company from RMB6,600,724 to RMB150,000,000 with the increased share capital of RMB143,399,276 from the share premium converted into 143,399,276 ordinary shares of RMB1 par value each, which were subscribed by and issued to the then shareholders of the Company in proportion to their respective equity interest in the Company (the “Share Conversion”); and (ii) adopt a restricted share scheme pursuant to which a total number of 521,313 restricted shares (before the Share Conversion) under Suzhou Hesheng Enterprise Management Consulting Partnership Enterprise (Limited Partnership)* (蘇州合升企業管理諮詢合夥企業(有限合夥)), representing 7.8978% of the total number of ordinary shares of the Company, shall be granted to its directors, supervisors, senior management and core employees (the “Grantees”) of the Group on the same date (the “Pre-[REDACTED] Restricted Share Scheme”). The subscription price for each restricted share is RMB6 (before the Share Conversion). The granted restricted share under the Pre-[REDACTED] Restricted Share Scheme may be vested in four tranches: (i) 25% vested on December 31, 2025; (ii) 25% vested on December 31, 2026; (iii) 25% vested on December 31, 2027; and (iv) 25% vested on December 31, 2028. On January 15, 2025, all the restricted shares under the Pre-[REDACTED] Restricted Share Scheme had been granted to the Grantees.

45. SUBSEQUENT FINANCIAL STATEMENTS

[No audited financial statements of the Group, the Company or any of its subsidiaries have been prepared in respect of any period subsequent to December 31, 2023 and up to the date of this report.]

* English name is for identification purpose only.

**APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS
ENDED SEPTEMBER 30, 2024**

The following is the text of a report set out on pages IB-1 to IB-19, received from the Company’s reporting accountants, Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.



**REPORT ON REVIEW OF CONDENSED CONSOLIDATED FINANCIAL
STATEMENTS TO THE BOARD OF DIRECTORS OF VIGONVITA LIFE SCIENCES
CO., LTD.**

Introduction

We have reviewed the condensed consolidated financial statements of Vigonvita Life Sciences Co., Ltd.* (“蘇州旺山旺水生物醫藥股份有限公司”) (the “Company”) and its subsidiaries (collectively referred to as the “Group”) set out on pages IB-3 to IB-19, which comprise the condensed consolidated statement of financial position as at September 30, 2024 and the related condensed consolidated statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the nine-month period then ended, and notes to the condensed consolidated financial statements. The condensed consolidated financial statements have been prepared by the directors of the Company solely for the purpose of application of [REDACTED] of the shares of the Company on The Stock Exchange of Hong Kong Limited. As a result, the condensed consolidated financial statements may not be suitable for another purpose. The directors of the Company are responsible for the preparation and presentation of these condensed consolidated financial statements in accordance with International Accounting Standard 34 “Interim Financial Reporting” (“IAS 34”) issued by the International Accounting Standards Board. Our responsibility is to express a conclusion on these condensed consolidated financial statements based on our review, and to report our conclusion solely to you, as a body, in accordance with our agreed terms of engagement, and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report.

Scope of Review

We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants. A review of these condensed consolidated financial statements consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted

* English name is for identification purpose only.

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

	NOTES	Nine months ended September 30,	
		2024	2023
		RMB'000 (unaudited)	RMB'000 (unaudited)
Revenue	4	9,996	194,387
Cost of sales		(6,210)	(5,399)
Gross profit		3,786	188,988
Other income	5	7,271	2,284
Other gains and losses, net	6	176	(4)
Research and development expenses		(100,481)	(102,007)
Administrative expenses		(50,936)	(39,425)
Selling expenses		(2,933)	(776)
Impairment losses under expected credit loss (“ECL”) model, net of reversal	18	(1,269)	(2,673)
[REDACTED]		[REDACTED]	[REDACTED]
Finance costs	7	(11,986)	(4,016)
(Loss) profit before tax	8	(156,372)	42,371
Income tax expense	9	–	–
(Loss) profit for the period		<u>(156,372)</u>	<u>42,371</u>
Other comprehensive (expenses) income			
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		(240)	(209)
Total comprehensive (expenses) income for the period		<u>(156,612)</u>	<u>42,162</u>
(Loss) profit for the period attributable to:			
Owners of the Company		(150,866)	48,510
Non-controlling interests		(5,506)	(6,139)
		<u>(156,372)</u>	<u>42,371</u>
Total comprehensive (expense) income for the period attributable to:			
Owners of the Company		(151,106)	48,301
Non-controlling interests		(5,506)	(6,139)
		<u>(156,612)</u>	<u>42,162</u>
(Loss) earnings per share	10		
– Basic (RMB yuan)		(1.04)	0.34
– Diluted (RMB yuan)		(1.04)	N/A

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT SEPTEMBER 30, 2024

	<i>NOTES</i>	At September 30, 2024	At December 31, 2023
		<i>RMB'000 (unaudited)</i>	<i>RMB'000 (audited)</i>
Non-current assets			
Property, plant and equipment	<i>12</i>	325,601	309,082
Right-of-use assets	<i>12</i>	128,499	126,277
Intangible assets	<i>12</i>	76,735	68,074
Other non-current assets	<i>13</i>	31,299	6,679
		<u>562,134</u>	<u>510,112</u>
Current assets			
Inventories	<i>14</i>	4,345	3,209
Trade receivables	<i>15</i>	12,550	36,552
Prepayments and other receivables	<i>16</i>	6,977	6,639
Contract assets	<i>17</i>	833	2,414
Other current assets	<i>19</i>	34,973	21,396
Bank balances and cash	<i>20</i>	95,052	95,974
		<u>154,730</u>	<u>166,184</u>
Current liabilities			
Trade and other payables	<i>21</i>	108,435	123,176
Contract liabilities		4,748	6,961
Amounts due to a related party	<i>26(ii)</i>	11,171	10,882
Lease liabilities		11,499	10,860
Financial liabilities at amortised cost	<i>23</i>	51,245	–
Borrowings	<i>22</i>	167,749	133,751
Deferred income		12,945	179
		<u>367,792</u>	<u>285,809</u>
Net current liabilities		<u>(213,062)</u>	<u>(119,625)</u>
Total assets less current liabilities		<u>349,072</u>	<u>390,487</u>
Non-current liabilities			
Lease liabilities		32,842	30,642
Borrowings	<i>22</i>	199,610	145,775
Deferred income		13,054	25,954
		<u>245,506</u>	<u>202,371</u>
Net assets		<u>103,566</u>	<u>188,116</u>
Capital and reserves			
Share capital	<i>24</i>	6,526	6,361
Reserves		112,524	192,733
Equity attributable to owners of the Company		119,050	199,094
Non-controlling interests		<u>(15,484)</u>	<u>(10,978)</u>
Total equity		<u>103,566</u>	<u>188,116</u>

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

	Attributable to owners of the Company										
	Paid-in capital	Share capital	Capital reserve	Share premium	Other reserve	Share-based payments reserve	Translation reserve	(Accumulated losses) retained earnings	Subtotal	Non-controlling interests	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
As at January 1, 2023 (unaudited)	6,361	-	348,639	-	-	63,320	302	(246,077)	172,545	(5,316)	167,229
Profit (loss) for the period	-	-	-	-	-	-	-	48,510	48,510	(6,139)	42,371
Other comprehensive expense for the period	-	-	-	-	-	-	(209)	-	(209)	-	(209)
Total comprehensive income (expense) for the period	-	-	-	-	-	-	(209)	48,510	48,301	(6,139)	42,162
Conversion into a joint stock company (Note 24)	(6,361)	6,361	(348,639)	176,701	-	(62,092)	-	234,030	-	-	-
Recognition of equity-settled share-based payments (Note 25)	-	-	-	-	-	11,062	-	-	11,062	-	11,062
As at September 30, 2023 (unaudited)	-	6,361	-	176,701	-	12,290	93	36,463	231,908	(11,455)	220,453
As at January 1, 2024 (audited)	-	6,361	-	176,701	-	15,973	17	42	199,094	(10,978)	188,116
Loss for the period	-	-	-	-	-	-	-	(150,866)	(150,866)	(5,506)	(156,372)
Other comprehensive expense for the period	-	-	-	-	-	-	(240)	-	(240)	-	(240)
Total comprehensive expense for the period	-	-	-	-	-	-	(240)	(150,866)	(151,106)	(5,506)	(156,612)
Issue of Series C shares (Note 24)	-	165	-	109,835	-	-	-	-	110,000	-	110,000
Recognition of redemption liabilities on Series C financing (Note 23)	-	-	-	-	(50,000)	-	-	-	(50,000)	-	(50,000)
Recognition of equity-settled share-based payments (Note 25)	-	-	-	-	-	11,062	-	-	11,062	-	11,062
Capital injection from a non-controlling interest	-	-	-	-	-	-	-	-	-	1,000	1,000
As at September 30, 2024 (unaudited)	-	6,526	-	286,536	(50,000)	27,035	(223)	(150,824)	119,050	(15,484)	103,566

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
NET CASH (USED IN) FROM OPERATING ACTIVITIES	(104,466)	44,165
INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(65,768)	(62,610)
Purchase of intangible assets	(8,784)	(15,909)
Payments for right-of-use assets	–	(46,360)
Payments for rental deposits	(213)	(233)
Proceeds on from disposal of financial assets at fair value through profit or loss (“FVTPL”)	100,179	–
Purchases of financial assets at FVTPL	(100,000)	–
NET CASH USED IN INVESTING ACTIVITIES	(74,586)	(125,112)
FINANCING ACTIVITIES		
Interest paid	(10,834)	(7,526)
Proceeds from borrowings	188,095	126,349
Repayments of borrowings	(100,227)	(53,208)
Repayments of lease liabilities	(10,117)	(5,861)
Proceeds from issue of Series C shares	110,000	–
Capital injection from a non-controlling interest	1,000	–
NET CASH FROM FINANCING ACTIVITIES	177,917	59,754
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,135)	(21,193)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	95,974	149,429
Effect of foreign exchange rate changes	213	16
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	95,052	128,252

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

1. GENERAL INFORMATION

Vigonvita Life Sciences Co., Ltd. (the “Company”) was incorporated in the People’s Republic of China (the “PRC”) on January 21, 2013 as a limited liability company. On March 10, 2023, the Company was converted to a joint stock company with limited liability under the Company Law of the PRC. The respective address of the registered office and the principal place of business of the Company are set out in the section headed “Corporate Information” to the document dated [●] (the “Document”).

The Group is an innovation-driven biopharmaceutical company dedicated to meeting clinical needs in the treatment of neuropsychiatric, infectious and andrological diseases.

The condensed consolidated financial statements are presented in Renminbi (“RMB”), which is also the functional currency of the Company.

2. BASIS OF PREPARATION

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 (“IAS 34”) “Interim Financial Reporting” issued by the International Accounting Standards Board as well as with the applicable disclosure requirements of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Going concern assessment

As at September 30, 2024, the Group’s net current liabilities were RMB213,062,000 and accumulated losses were RMB150,824,000. Meanwhile, the Group’s total borrowings amounted to RMB367,359,000 as at September 30, 2024, of which RMB167,749,000 will be due for repayment within the next twelve months. In addition, the Group’s bank balances and cash were amounted to RMB95,052,000, whilst the Group’s current liabilities were amounted to RMB367,792,000 as at September 30, 2024.

Since (i) the Group had unutilised banking facilities of RMB341,000,000 as at September 30, 2024, of which RMB40,000,000 could be utilised for daily operating and RMB301,000,000 could be utilised for construction in progress, (ii) the redemption liabilities on ordinary shares of RMB51,245,000 recognised as financial liabilities at amortised cost as at September 30, 2024 as set out in Note 23 to the condensed consolidated financial statements were derecognised and credited to other reserve on December 23, 2024, as the corresponding redemption obligation was terminated with counterparty on this date, and (iii) the Company had received remaining proceeds of RMB50,000,000 for Series C shares on December 23, 2024. The Group has prepared cash flow projections which cover a period from October 1, 2024 to June 30, 2026. The directors of the Company are of the opinion that, taking into account the above proceeds from financing and unutilised bank facilities, as well as other possible financing options, the Group will have sufficient working capital to fund its operations and to meet its payment obligations including the milestone payment of in-licenses and capital commitment when they fall due from October 1, 2024 to June 30, 2026. Accordingly, the directors of the Company are satisfied that it is appropriate to prepare the condensed consolidated financial statements of the Group for the nine months ended September 30, 2024 on a going concern basis.

3. MATERIAL ACCOUNTING POLICY INFORMATION

The condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments, which are measured at fair values, as appropriate.

The accounting policies and methods of computation used in the condensed consolidated financial statements for the nine months ended September 30, 2024 are the same as those presented in the Historical Financial Information included in the accountants’ report as set out in Appendix IA to the Document.

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

4. REVENUE AND SEGMENT INFORMATION

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Timing of revenue recognition		
<i>A point in time</i>		
Out-licensing income	5,382	191,495
Sales of pharmaceutical products	582	674
	<u>5,964</u>	<u>192,169</u>
<i>Over time</i>		
Contract research organisation (“CRO”) services	4,032	2,218
	<u>9,996</u>	<u>194,387</u>
Geographical market		
The PRC	9,984	193,713
Uzbekistan	12	674
	<u>9,996</u>	<u>194,387</u>

Segment information

For the purpose of resources allocation and performance assessment, the Group’s management, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole. The Group has only one reportable segment.

5. OTHER INCOME

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Government grants (<i>Note</i>)	6,682	1,138
Bank interest income	562	985
Others	27	161
	<u>7,271</u>	<u>2,284</u>

Note: The amount represents subsidies granted by the PRC government authorities as incentives mainly for the Group’s research and development activities. The government grants including unconditional and conditional which had been approved by the PRC government authorities. The unconditional government grants are recognised when payments were received. The conditional government grants are recognised when condition met and the corresponding grants are received.

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

6. OTHER GAINS AND LOSSES, NET

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Net foreign exchange gains	213	16
Gains arising from financial assets at FVTPL	179	–
Losses on lease modification	(154)	–
Others	(62)	(20)
	<u>176</u>	<u>(4)</u>

7. FINANCE COSTS

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Interest on borrowings	9,471	6,609
Less: amounts capitalised in the cost of construction in progress	348	3,917
	<u>9,123</u>	<u>2,692</u>
Interest on lease liabilities	1,329	1,035
Interest on financial liabilities at amortised cost	1,245	–
Interest on loan from a related party (<i>Note 26(i)</i>)	289	289
	<u>11,986</u>	<u>4,016</u>

8. (LOSS) PROFIT FOR THE PERIOD

(Loss) profit before tax for the period has been arrived at after charging:

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Depreciation of property, plant and equipment	15,089	4,552
Depreciation of right-of-use assets	10,581	8,002
Amortisation of intangible assets	378	11
Total depreciation and amortisation	26,048	12,565
Less: amounts capitalised in the cost of construction in progress	1,437	327
	<u>24,356</u>	<u>12,238</u>
Auditors' remuneration	59	800
Cost of inventories recognised as an expense		
– research and development expenses	5,541	7,043
– costs of sales	306	717
Directors' and supervisors' emoluments	13,119	12,957
Other staffs costs:		
– salaries and other benefits	44,148	41,775
– discretionary bonus (<i>Note</i>)	2,540	1,992
– retirement benefit scheme contributions	5,562	4,483
Total staff costs (including directors' emoluments)	<u>65,369</u>	<u>61,207</u>

Note: Discretionary bonus is determined based on their duties and responsibilities of the relevant individuals within the Group and the Group's performance.

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

9. INCOME TAX EXPENSE

No provision for income tax expense has been made since the Company and its subsidiaries have no assessable profits for both periods.

10. (LOSS) EARNINGS PER SHARE

The calculation of the basic and diluted (loss) earnings per share is based on the following data:

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
(Loss) earnings		
(Loss) earnings for the purpose of basic loss per share for the period attributable to owners of the Company	<u>(150,866)</u>	<u>48,510</u>
	<i>'000</i>	<i>'000</i>
Number of shares		
Weighted average number of ordinary shares for the purpose of basic (loss) earnings per share (<i>Note</i>)	<u>145,110</u>	<u>144,558</u>
	<i>RMB</i>	<i>RMB</i>
Basic (loss) earnings per share	<u>(1.04)</u>	<u>0.34</u>

Note: One investor’s shares, which are recorded as financial liabilities at amortised cost as set out in Note 23 to the condensed consolidated financial statements, are not treated as outstanding shares and thus are excluded in the calculation of basic loss per share until the redemption right was legally terminated on December 23, 2024.

The weighted average number of ordinary shares for the purpose of basic earnings per share has also been adjusted retrospectively for the share conversion on January 13, 2025 as set out in Note 29 to the condensed consolidated financial statements on the assumption that the share conversion had been effective at the beginning of the current period.

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the nine months ended September 30, 2024, the Company had one investor’s shares which are potential ordinary shares. As the Group incurred losses for the nine months ended September 30, 2024, the potential ordinary shares were not included in the calculation of diluted loss per share, as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the nine months ended September 2024 is the same as basic loss per share for the period.

No diluted (loss) earnings per share for the nine months ended September 30, 2023 was presented as there were no potential ordinary shares in issue for this period.

11. DIVIDENDS

No dividend was paid, declared or proposed for the shareholders of the Company during the nine months ended September 30, 2024 (nine months ended September 30, 2023: nil), nor has any dividend been proposed since the end of the reporting period.

12. PROPERTY, PLANT AND EQUIPMENT, RIGHT-OF-USE ASSETS AND INTANGIBLE ASSETS

The Group incurred approximately RMB2,152,000 and RMB28,908,000 for the nine months ended September 30, 2024 (nine months ended September 30, 2023: RMB9,577,000 and RMB56,019,000), for acquisition of machinery and equipment and construction costs for plant and office premise.

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

During the nine months ended September 30, 2024, the construction of a plant had been completed and construction in progress of RMB242,781,000 was transferred to building, machinery and equipment and office equipment (nine months ended September 30, 2023: RMB26,041,000).

During the nine months ended September 30, 2024, the Group entered into one new lease agreement for office premise with lease term of 5 years (nine months ended September 30, 2023: 3 to 6 years). On date of lease commencement, the Group recognised right-of-use assets of RMB14,469,000 (nine months ended September 30, 2023: RMB17,214,000) and lease liabilities of RMB14,469,000 (nine months ended September 30, 2023: RMB17,168,000).

During the nine months ended September 30, 2024, the Group made milestone payment of RMB2,160,000 (nine months ended September 30, 2023: RMB8,780,000) upon the milestone criteria met as determined in the corresponding in-licensing agreements.

During the nine months ended September 30, 2024, internally researched and developed generic drug (Dapoxetine) amounted to RMB13,816,000 (nine months ended September 30, 2023: nil) is commercialised and amortised when ready for use over the estimated economic life of 10 years.

As at September 30, 2024, the management is not aware of any significant adverse changes on the respective cash-generating unit that indicates the carrying amount of the cash-generating unit exceeds its recoverable amount. As a result, no impairment assessment as at September 30, 2024 was performed.

13. OTHER NON-CURRENT ASSETS

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
Prepayments for property, plant and equipment	29,347	492
Long-term deposits	1,952	1,738
VAT recoverable	—	4,449
	31,299	6,679

14. INVENTORIES

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
Raw materials and consumables	3,411	3,174
Work in progress	175	—
Finished goods	759	35
	4,345	3,209

15. TRADE RECEIVABLES

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
Trade receivables	14,285	38,773
Less: allowance for credit losses	1,735	2,221
	12,550	36,552

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

The following is an aged analysis of trade receivable net of allowance for credit losses presented based on the invoice date at the end of the reporting period:

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
1 to 30 days	12,002	16,174
31-60 days	–	20,000
61-90 days	4	–
91-120 days	157	–
121 to 180 days	19	45
Over 360 days	368	333
	<u>12,550</u>	<u>36,552</u>

The Group normally grants a credit period of 30 to 60 days or a particular period agreed with third party customers effective from the date when the services have been completed or control of goods has been transferred to the customer and billed to the customer. For certain trade receivables balances which have been past due more than 90 days, the directors of the Company consider they are not in default since such balances could be recovered based on the historical repayment pattern of overdue trade receivables and the financial conditions of corresponding customers.

16. PREPAYMENTS AND OTHER RECEIVABLES

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
Prepayments for purchase of materials and research and development services	5,684	4,117
Other receivables	345	2,263
Less: allowance for credit losses	<u>12</u>	<u>113</u>
	333	2,150
Deposits	578	242
Prepayments for short-term rental and property management fee	177	130
Others	<u>205</u>	<u>–</u>
	<u>6,977</u>	<u>6,639</u>

17. CONTRACT ASSETS

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
<u>CRO services</u>		
Contract assets	1,010	3,383
Less: allowance for credit losses	<u>177</u>	<u>969</u>
	<u>833</u>	<u>2,414</u>

The Group classifies these contract assets as current because the Group expects to realise them in its normal operating cycle.

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

18. IMPAIRMENT ASSESSMENT ON FINANCIAL ASSETS AND OTHER ITEMS SUBJECT TO EXPECTED CREDIT LOSS (“ECL”) MODEL

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Impairment loss recognised/(reversed) in respect of		
– trade receivables	1,914	2,435
– other receivables	(101)	141
– contract assets	(544)	97
	<u>1,269</u>	<u>2,673</u>

The basis of determining the inputs and assumptions and the estimation techniques used in the condensed consolidated financial statements for the nine months ended 30 September 2024 are the same as those followed in the Historical Financial Information included in the accountants’ report as set out in Appendix IA to the Document.

19. OTHER CURRENT ASSETS

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
	VAT recoverable	<u>34,973</u>

20. BANK BALANCES AND CASH

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
	Bank balances	95,033
Cash on hand	19	32
	<u>95,052</u>	<u>95,974</u>

Bank balances held by the Group carry interests at market rates ranging from 0.20% to 1.20% as at September 30, 2024 (December 31, 2023: 0.25% to 2.00%).

The carrying amounts of the Group’s bank balances and cash denominated in currencies other than functional currencies of the relevant group entities at the end of the reporting period are as follows:

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
	USD	<u>1,526</u>

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

21. TRADE AND OTHER PAYABLES

	<u>At September 30, 2024</u>	<u>At December 31, 2023</u>
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
Trade payables for research and development expenses	1,083	615
Accrued research and development expenses	19,576	19,710
Payables for construction in progress	74,982	85,884
Accrued staff costs and benefits	8,148	9,549
Payables in respect of acquisition of intangible assets	2,750	2,750
Payables for machineries and equipment	923	2,406
Other tax payables	629	1,590
Deposits	344	672
	<u>108,435</u>	<u>123,176</u>

The following is an aged analysis of trade payables presented based on the invoice dates at the end of the reporting period is as follows:

	<u>At September 30, 2024</u>	<u>At December 31, 2023</u>
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
0-30 days	626	256
31-90 days	28	16
91-180 days	235	46
181-365 days	14	153
Over 365 days	180	144
	<u>1,083</u>	<u>615</u>

The average credit period granted by suppliers is normally 30 to 60 days.

22. BORROWINGS

	<u>At September 30, 2024</u>	<u>At December 31, 2023</u>
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
<u>At amortised cost</u>		
Bank loans	356,892	263,614
Other loan in respect of sale and leaseback arrangement	10,467	15,912
	<u>367,359</u>	<u>279,526</u>
Secured	155,597	126,911
Unsecured	211,762	152,615
	<u>367,359</u>	<u>279,526</u>
The carrying amounts of the above borrowings are repayable:		
Within one year	167,749	133,751
Within a period of more than one year but not exceeding two years	127,060	74,706
Within a period of more than two years but not exceeding five years	72,550	71,069
	<u>367,359</u>	<u>279,526</u>
Less: Amount due within one year shown under current liabilities	167,749	133,751
Amount shown under non-current liabilities	<u>199,610</u>	<u>145,775</u>

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

Secured bank loans are pledged by land use rights, the building and construction in progress on the corresponding land use rights owned by the Group amounted to RMB83,806,000, RMB227,561,000 and RMB41,177,000 respectively as at September 30, 2024 (December 31, 2023: land use rights and the construction in progress on the corresponding land use rights of RMB85,735,000 and RMB255,451,000, respectively). In addition, the secured bank loan of a subsidiary of the Group is guaranteed by the Company.

The interest rate of the borrowings ranged from 2.8% to 5.4% per annum.

23. REDEMPTION LIABILITIES ON ORDINARY SHARES

From April 2024 to September 2024, the Company entered into share subscription agreements with several independent investors and a relative investor (“Series C Investors”), pursuant to which the investors shall make an aggregate investment of RMB160,000,000 in the Company as consideration for the subscription of 239,482 new ordinary shares issued by the Company. As at September 30, 2024, the Company had received proceeds of RMB110,000,000 for Series C shares. The remaining proceeds of RMB50,000,000 for 74,838 shares had been received on December 23, 2024.

One of Series C Investors was entitled to a redemption right, upon the occurrence of the event that the Company could not complete the shares subscription with other Series C Investors and receive proceeds of more than RMB100,000,000 by the end of May 2024. If the Company fails to meet this condition, such Series C Investor has the right to terminate the share subscription agreement with the Company and requests the Company to return the paid investment at the amount of the original subscription price plus a yield at 0.15% per day. As at September 30, 2024, such Series C Investor invested RMB50,000,000 as the subscription price for Series C shares and the Company was liable for the redemption obligation, which was recognised as the financial liabilities at amortised cost of RMB51,245,000.

On December 23, 2024, the Company signed a supplementary agreement with such Series C Investor to terminate aforementioned redemption right. Accordingly, the amounts of the financial liabilities at amortised cost were derecognised and credited to other reserve in December 2024.

24. SHARE CAPITAL

As disclosed in Note 1, the Company converted into a joint stock company on March 10, 2023, the balance as at January 1, 2023 represented the paid-in capital of the Company prior to the conversion of the Company. Share capital as at December 31, 2023 and September 30, 2024 represented the issued share capital of the Company.

Paid-in capital

	<u>Paid-in capital</u>
	<i>RMB'000</i>
Issued and paid	
As at January 1, 2023	6,361
Conversion into a joint stock company (<i>Note</i>)	<u>(6,361)</u>
As at December 31, 2023	<u>–</u>

Share capital

	<u>Number of shares</u>	<u>Nominal value of shares</u>
		<i>RMB'000</i>
Ordinary shares of RMB1 each		
Authorised and issued		
As at January 1, 2023	–	–
Conversion into a joint stock company (<i>Note</i>)	<u>6,361,242</u>	<u>6,361</u>
As at December 31, 2023	<u>6,361,242</u>	<u>6,361</u>

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

	<u>Number of shares</u>	<u>Nominal value of shares</u> <i>RMB'000</i>
Authorised		
As at January 1, 2024 (audited)	6,361,242	6,361
Issue of Series C shares (<i>Note 23</i>)	<u>239,482</u>	<u>239</u>
As at September 30, 2024 (unaudited)	<u>6,600,724</u>	<u>6,600</u>
	<u>Number of shares</u>	<u>Shown in the condensed consolidated statements of financial position</u> <i>RMB'000</i>
Issued and fully paid		
As at January 1, 2024 (audited)	6,361,242	6,361
Issue of Series C shares (<i>Note 23</i>)	<u>164,644</u>	<u>165</u>
As at September 30, 2024 (unaudited)	<u>6,525,886</u>	<u>6,526</u>

Note: On March 10, 2023, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC. The net assets of the Company as of the conversion date of November 30, 2022, including paid-in capital, reserves and accumulated losses, amounting to approximately RMB183,062,000 were converted into 6,361,242 shares with a nominal value of RMB1.00 each. The excess of net assets converted over nominal value of the ordinary shares was credited to the Company’s share premium.

25. SHARE-BASED PAYMENT TRANSACTIONS

Restricted shares scheme

The restricted shares issued under the Suzhou Nanbowan Enterprise Management Consulting Partnership (Limited Partnership) restricted shares scheme, which are disclosed in Note 35 to the Historical Financial Information included in the accountants’ report as set out in Appendix IA to the Document, has no change for the nine months ended September 30, 2024.

The following table summarised the movement of the Group’s unvested restricted shares:

	<u>Unvested registered capital</u> <i>'000</i>	<u>Weighted average grant date fair value per registered capital</u> <i>RMB</i>
Unvested as at January 1, 2023 (unaudited), September 30, 2023 (unaudited), December 31, 2023 (audited) and September 30, 2024 (unaudited)	<u>350</u>	<u>168.54</u>

The Group has recognized share-based payment expenses of RMB11,062,000 for the nine months ended September 30, 2024 (nine months ended September 30, 2023: RMB11,062,000).

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

26. RELATED PARTY TRANSACTIONS

- (i) Other than as disclosed elsewhere in the condensed consolidated financial statements, the Group has the following transactions with its fellow subsidiaries under the common control of the founder of the Company during both periods.

Purchase of pharmaceutical ingredient with ancillary service from related parties

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Topharman Shandong	1,107	9,012

Interests on loan from a related party

	Nine months ended September 30,	
	2024	2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(unaudited)</i>
Topharman Shanghai	289	289

- (ii) Other than as disclosed elsewhere in the condensed consolidated financial statements, as at the end of the reporting period, the Group had balances with related parties as follows, which are all unsecured, as follows:

Trade payables

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
	Topharman Shandong	6,653
Topharman Shanghai	2,750	2,750
	9,403	8,847

Amounts due to a related party

	At September 30, 2024	At December 31, 2023
	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i> <i>(audited)</i>
	Topharman Shanghai	11,171

Note: The amounts due to Topharman Shanghai are loans from Topharman Shanghai to Nantong Hefeng Lianwang Pharmaceutical Technology Co., Ltd.* (南通和風連旺醫藥科技有限公司), a non-wholly owned subsidiary of the Company, with a fixed interest rate of 3.85%. According to the original loan agreement, the principal of RMB10,000,000 and corresponding interests are fully repayable in 2024. In 2024, the Company signed the supplementary agreements with Topharman Shanghai to extend the final repayment date to September 30, 2025. Therefore, the amounts due to Topharman Shanghai were classified as current liabilities in the condensed consolidated statement of financial position as at September 30, 2024. The Group expects to settle the amount due to a related party before of the [REDACTED] of H Shares of the Company on the Stock Exchange.

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

Compensation of key management personnel

The remuneration of directors and supervisors of the Company and other members of key management was as follows:

	Nine months ended September 30,	
	2024	2023
	RMB'000 (unaudited)	RMB'000 (unaudited)
Salaries and other benefits	3,760	3,607
Retirement benefits scheme contribution	290	273
Discretionary bonus (<i>Note</i>)	631	631
Share-based payments	11,062	11,062
	<u>15,743</u>	<u>15,573</u>

Note: Discretionary bonus is determined based on their duties and responsibilities of the relevant individuals within the Group and the Group's performance.

27. CAPITAL COMMITMENT

	At September 30, 2024	At December 31, 2023
	RMB'000 (unaudited)	RMB'000 (audited)
Capital expenditure contracted for but not provided in the condensed consolidated financial statements: – acquisition of property, plant and equipment	<u>257,366</u>	<u>100,286</u>

28. FAIR VALUE MEASUREMENTS OF FINANCIAL INSTRUMENTS

Fair value of the Group's financial assets that are measured at fair value on a recurring basis

The fair value of financial assets (in particular, the valuation technique(s) and inputs used), as well as the level of the fair value hierarchy into which the fair value measurements are categorised (Levels 1 to 3) based on the degree to which the inputs to the fair value measurements is observable.

- Level 1 fair value measurements are based on quoted prices (unadjusted) in active market for identical assets or liabilities;
- Level 2 fair value measurements are those derived from inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices); and
- Level 3 fair value measurements are those derived from valuation techniques that include inputs for the asset or liability that are not based on observable market data (unobservable inputs).

As at September 30, 2024, the amount financial assets at FVTPL of the Group is RMB nil (December 31, 2023: RMB nil).

APPENDIX IB FINANCIAL INFORMATION FOR NINE MONTHS ENDED SEPTEMBER 30, 2024

Reconciliation of Level 3 fair value measurements of financial assets:

	Financial assets at FVTPL
	<i>RMB'000</i>
As at January 1, 2023 (unaudited), September 30, 2023 (unaudited) and December 31, 2023 (audited)	–
Fair value gain:	
– in profit or loss	179
Purchased	100,000
Disposals	<u>(100,179)</u>
As at September 30, 2024 (unaudited)	<u>–</u>

Financial assets at FVTPL held by the Group for the current reporting period are structured deposits. Total gains or losses for the period included in profit or loss, no unrealised gain or loss relates to financial assets at FVTPL held at the end of current reporting period (nine months ended 30 September 2023: nil). Fair value gains or losses on financial assets at FVTPL are included in “other gains and losses”.

Fair value of the Group’s financial assets and liabilities that are not measured at fair value on a recurring basis (but fair value disclosures are required)

The directors of the Company consider that the carrying amount of the Group’s financial assets and financial liabilities recorded at amortised cost in the condensed consolidated financial statements approximate their fair values.

29. EVENTS AFTER THE END OF THE REPORTING PERIOD

On January 13, 2025, the Company passed a shareholders’ resolution to (i) increase the share capital of the Company from RMB6,600,724 to RMB150,000,000 with the increased share capital of RMB143,399,276 from the share premium converted into 143,399,276 ordinary shares of RMB1 par value each, which were subscribed by and issued to the then shareholders of the Company in proportion to their respective equity interest in the Company (the “Share Conversion”); and (ii) adopt a restricted share scheme pursuant to which a total number of 521,313 restricted shares (before the Share Conversion) under Suzhou Hesheng Enterprise Management Consulting Partnership Enterprise (Limited Partnership)* (蘇州合升企業管理諮詢合夥企業(有限合夥)), representing 7.8978% of the total number of ordinary shares of the Company, shall be granted to its directors, supervisors, senior management and core employees (the “Grantees”) of the Group on the same date (the “Pre-[REDACTED] Restricted Share Scheme”). The subscription price for each restricted share is RMB6 (before the Share Conversion). The granted restricted share under the Pre-[REDACTED] Restricted Share Scheme may be vested in four tranches: (i) 25% vested on December 31, 2025; (ii) 25% vested on December 31, 2026; (iii) 25% vested on December 31, 2027; and (iv) 25% vested on December 31, 2028. On January 15, 2025, all the restricted shares under the Pre-[REDACTED] Restricted Share Scheme had been granted to the Grantees.

* English name is for identification purpose only.

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX III

VALUATION REPORT

The following is the text of a letter, a summary of values and valuation certificates prepared for the purpose of incorporation in this document received from AVISTA Valuation Advisory Limited, an independent valuer, in connection with its valuation as at 30 November 2024 of the property interests held by the Group.



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27 January 2025

The Board of Directors

Vigonvita Life Sciences Co., Ltd. (蘇州旺山旺水生物醫藥股份有限公司)

8th Floor, Building A

No. 108, Yuxin Road

Suzhou Industrial Park District

Suzhou, PRC

Dear Sirs/Madams,

INSTRUCTIONS

In accordance with the instructions of Vigonvita Life Sciences Co., Ltd. (蘇州旺山旺水生物醫藥股份有限公司) (the “Company”) and its subsidiaries (hereinafter together referred to as the “Group”) for us to carry out the valuation of the property interests (the “Properties”) located in the People’s Republic of China (the “PRC”) held by the Group, we confirm that we have carried out inspection, made relevant enquiries and searches and obtained such further information as we consider necessary for the purpose of providing you with our opinion of the market value of the Properties as at 30 November 2024 (the “Valuation Date”).

BASIS OF VALUATION AND VALUATION STANDARDS

Our valuation is carried out on a market value basis, which is defined by the Royal Institution of Chartered Surveyors as “*the estimated amount for which an asset or liability should exchange on the valuation date between a willing buyer and a willing seller in an arm’s length transaction, after proper marketing and where the parties had each acted knowledgeably, prudently and without compulsion*”.

In valuing the Properties, we have complied with all the requirements set out in Chapter 5 and Practice Note 12 of the Rules Governing the Listing of Securities issued by The Stock Exchange of Hong Kong Limited (the “Listing Rules”), the RICS Valuation — Global Standards 2024 published by the Royal Institution of Chartered Surveyors (“RICS”) and the International Valuation Standards published from time to time by the International Valuation Standards Council.

APPENDIX III

VALUATION REPORT

CATEGORISATION OF PROPERTY INTERESTS

In the course of our valuation, the appraised Properties have been categorized according firstly to type of interests held by the Group, which in turn being classified into the following groups:

Group I — Property interests held for owner occupation by the Group in the PRC

Group II — Property interests held for development by the Group in the PRC

VALUATION ASSUMPTIONS

Our valuation of the Properties excludes an estimated price inflated or deflated by special terms or circumstances such as atypical financing, sale and leaseback arrangement, special considerations or concessions granted by anyone associated with the sale, or any element of special value or costs of sale and purchase or offset for any associated taxes.

No allowance has been made in our report for any charges, mortgages or amounts owing on any of the Properties valued nor for any expenses or taxation which may be incurred in effecting a sale. Unless otherwise stated, it is assumed that the Properties are free from encumbrances, restrictions and outgoings of an onerous nature, which could affect their values.

In the course of our valuation of the Properties in the PRC, we have relied on the advice given by the Group and its legal advisor, being JunHe LLP (君合律師事務所) (the “PRC Legal Advisor”), regarding the titles to the Properties.

In valuing the Properties, we have relied on a legal opinion regarding the Properties provided by the PRC Legal Adviser dated 27 January 2025 (the “PRC Legal Opinion”). Unless otherwise stated, the Group has legally obtained the land use rights of the Properties.

No environmental impact study has been ordered or made. Full compliance with applicable national, provincial and local environmental regulations and laws is assumed.

VALUATION METHODOLOGY

In valuing the property interests in Group I, due to the nature of the buildings and structures of the subject properties, there are no market sales comparables readily available. We have valued the property interests on the basis of their depreciated replacement cost. Depreciated replacement cost is defined as “*the current cost of replacing an asset with its modern equivalent asset less deduction for physical deterioration and all relevant forms of obsolescence and optimization*”. It is based on an estimation of the market value for the existing use of the land, plus the current cost of replacement (reproduction) of the building, including the improvements, less deductions for physical deterioration and all relevant forms of obsolescence and optimization.

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VALUATION REPORT

In valuing the property interests in Group II, where the corresponding property was under construction as at the Valuation Date, we have assumed that it will be developed and completed in accordance with the latest development proposals provided to us by the Group. We have assumed that approvals for the proposals have been obtained. In arriving at our opinion of values, we have adopted the comparison approach by making references to land comparable sales evidence as available in the relevant market and have also taken into account the accrued construction cost and professional fees relevant to the stage of construction as at the Valuation Date and the remainder of the cost and fees expected to be incurred for completing the developments. We have relied on the accrued construction cost and professional fees information provided by the Group for the different stages of construction of the subject property as at the Valuation Date, and we did not find any material inconsistency from those of other similar developments.

TITLE INVESTIGATION

We have been provided with copies of documents in relation to the title of the Properties in the PRC. Where possible, we have examined the original documents to verify the existing title to the Properties in the PRC and any material encumbrance that might be attached to the Properties or any tenancy amendment. All documents have been used for reference only and all dimensions, measurements and areas are approximate. In the course of our valuation, we have relied considerably on the PRC Legal Opinion given by the PRC Legal Adviser, concerning the validity of the title of the Properties in the PRC.

SITE INVESTIGATION

We have inspected the exteriors and, where possible, the interior of the subject properties. The site inspection was carried out between 10 November 2024 and 12 November 2024 by Bobby Chan (Assistant Manager). He is a chartered surveyor and has more than 5 years' experience in valuation of properties in the PRC.

In the course of our inspection, we did not note any serious defects. However, we have not carried out an investigation on site to determine the suitability of ground conditions and services for any development thereon, nor have we conducted structural surveys to ascertain whether the subject properties are free of rot, infestation, or any other structural defects. Additionally, no tests have been carried out on any of the utility services. Our valuation has been prepared on the assumption that these aspects are satisfactory. We have further assumed that there is no significant pollution or contamination in the locality which may affect any future developments.

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VALUATION REPORT

SOURCE OF INFORMATION

Unless otherwise stated, we shall rely to a considerable extent on the information provided to us by the Group or the PRC Legal Adviser or other professional advisers on such matters as statutory notices, planning approvals, zoning, easements, tenures, completion date of buildings, development proposal, identification of the properties, particulars of occupation, site areas, floor areas, matters relating to tenure, tenancies and all other relevant matters.

We have had no reason to doubt the truth and accuracy of the information provided to us by the Group. We have also sought confirmation from the Group that no material factors have been omitted from the information supplied. We consider that we have been provided with sufficient information to reach an informed view and we have no reason to suspect that any material information has been withheld.

We have not carried out detailed measurements to verify the correctness of the areas in respect of the properties but have assumed that the areas shown on the title documents and official site plans handed to us are correct. All documents and contracts have been used as reference only and all dimensions, measurements and areas are approximations. No on-site measurement has been taken.

LIMITING CONDITION

Wherever the content of this report is extracted and translated from the relevant documents supplied in Chinese context and there are discrepancies in wordings, those parts of the original documents will take prevalent.

CURRENCY

Unless otherwise stated, all monetary amounts stated in this report are in Renminbi (RMB).

Our valuations are summarized below, and the valuation certificates are attached.

Yours faithfully,
For and on behalf of
AVISTA Valuation Advisory Limited
Vincent C B Pang
MRICS CFA FCPA FCPA Australia
RICS Registered Valuer
Managing Partner

Note: Mr. Vincent C B Pang is a member of Royal Institution of Chartered Surveyors (RICS) and a registered valuer of RICS. He has over 10 years' experience in valuation of properties including Hong Kong, the PRC, the U.S., and East and Southeast Asia.

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VALUATION REPORT

SUMMARY OF VALUES

Group I — Property interests held for owner occupation by the Group in the PRC

No.	Property	Market value in existing state as at 30 November 2024	Interest Attributable to the Group	Market value Attributable to the Group as at 30 November 2024
		<i>RMB</i>		<i>RMB</i>
1.	West of Dapu Road and North of Huiyin Road, Lianyungang Economic and Technological Development Area, Lianyungang City, Jiangsu Province, the PRC (中國江蘇省連雲港市連雲港經濟技術開發區大浦路西、匯銀路北側)	296,780,000	100%	296,780,000
	Sub-total:	<u>296,780,000</u>		<u>296,780,000</u>

Group II — Property interests held for development by the Group in the PRC

No.	Property	Market value in existing state as at 30 November 2024	Interest Attributable to the Group	Market value Attributable to the Group as at 30 November 2024
		<i>RMB</i>		<i>RMB</i>
2.	West of Fenglipu and south of Songbei Road, Suzhou Industrial Park, Suzhou City, Jiangsu Province, the PRC (中國江蘇省蘇州市蘇州工業園區鳳裡浦西、淞北路南)	97,790,000	100%	97,790,000
	Sub-total:	<u>97,790,000</u>		<u>97,790,000</u>
	Grand-total:	<u>394,570,000</u>		<u>394,570,000</u>

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VALUATION REPORT

VALUATION CERTIFICATE

Group I — Property interests held for owner occupation by the Group in the PRC

No.	Property	Description and tenure	Particulars of occupancy	Market value in existing state as at 30 November 2024
				<i>RMB</i>
1.	West of Dapu Road and North of Huiyin Road, Lianyungang Economic and Technological Development Area, Lianyungang City, Jiangsu Province, the PRC (中國江蘇省連雲港市連雲港經濟技術開發區大浦路西、匯銀路北側)	The property comprises eight 1- to 6-storey industrial buildings, with a total gross floor area of approximately 51,955.11 sq.m. The property was held for owner occupation as at the Valuation Date. As advised by the Group, the property was completed in 2024. The property is located in Lianyungang Economic and Technological Development Area, with approximately 15.7 km to Lianyungang Railway Station and 38.9 km to Lianyungang Huaguoshan International Airport. The land use rights of the property have been granted for a term expiring on 16 January 2070 for industrial use.	The property was occupied by the Group as at the Valuation Date for manufacturing and office purpose.	296,780,000 (100% interest attributable to the Group: 296,780,000)

Notes:

- Pursuant to State-owned Construction Land Use Right Transfer Contract (國有建設用地使用權出讓合同) — No. 3207012020CR0010 dated 2 January 2020 issued by the Lianyungang Municipal Bureau of Natural Resources and Planning (連雲港市自然資源和規劃局), the land use rights of a parcel of land with a site area of approximately 133,157.00 sq.m. have been granted to Vigonvita (Lianyungang) Pharmaceutical Co., Ltd. (旺山旺水(連雲港)製藥有限公司, “Vigonvita Lianyungang”), in which the Group holds a direct ownership stake of 100%, for a term of 50 years for industrial use at a total land premium of approximately RMB31,700,000.

As revealed from the aforesaid State-owned Construction Land Use Right Transfer Contract, the property is subject to the following material development conditions:

Permitted Use	:	Industrial
Plot Ratio	:	≥ 1.0 and ≤ 2.0
Maximum Permitted Accountable Gross Floor Area	:	266,314.00 sq.m.
Site Coverage	:	≤ 55%
Height Restriction	:	≤ 36m
Greening Rate	:	≤ 15%
Building Covenant	:	To commence construction before 31 July 2020 and to complete construction before 30 July 2022
Other Material Restrictions	:	—

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2. Pursuant to 8 Real Estate Ownership Certificates issued by Lianyungang Municipal Bureau of Natural Resources and Planning (連雲港市自然資源和規劃局), the land use rights and building ownership of the property have been vested in Vigonvita Lianyungang, in which the Group holds a direct ownership stake of 100%, with the details as follows:

No.	Certificate No.	Land Usage	Building Usage	Expiry Date	Site Area (sq.m.)	Gross Floor Area (sq.m.)
1	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053814	Industrial	Industrial	16 January 2070	133,157.00	15,085.41
2	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053815	Industrial	Industrial	16 January 2070	133,157.00	747.13
3	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053816	Industrial	Industrial	16 January 2070	133,157.00	9,596.52
4	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053817	Industrial	Industrial	16 January 2070	133,157.00	187.01
5	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053818	Industrial	Industrial	16 January 2070	133,157.00	737.57
6	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053819	Industrial	Industrial	16 January 2070	133,157.00	11,464.52
7	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053820	Industrial	Industrial	16 January 2070	133,157.00	12,628.01
8	Su (2024) Lian Yun Gang Shi Bu Dong Chan Quan Di No. 0053821	Industrial	Industrial	16 January 2070	133,157.00	1,508.94
Total:					133,157.00	51,955.11

3. As advised by the Group, the details of the property are set out as below:

Classification	Usage	Gross Floor Area (sq.m.)
Group I — Property interests held for owner occupation by the Group in the PRC	Industrial	50,446.17
	Ancillary	1,508.94
Total:		51,955.11

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4. We have been provided with the PRC Legal Opinion, which contains, inter alia, the following: –
 - a. Vigonvita Lianyungang has legally and validly obtained the land use rights and the building ownership of the property under the terms of the Real Estate Ownership Certificates;
 - b. Vigonvita Lianyungang has the right to freely occupy, use, lease, or dispose of the property; and
 - c. The property has been pledged to Suzhou Branch of Shanghai Pudong Development Bank Co., Ltd. (上海浦東發展銀行股份有限公司蘇州分行).
5. Our valuation has been made on the following basis and analysis:

In our valuation of the land use rights, we have considered and analyzed 3 land sale comparables in the vicinity. The adjusted site values of the land sales range from RMB238 to RMB239 per sq.m. for industrial use. The unit rate adopted in the valuation is consistent with the unit rates of the relevant comparables after due adjustments in terms of location, time and size, etc.

Regarding the building portion, the current replacement cost of the building is assessed by determining the construction cost of a modern substitute building with the same service capacity as the building which is being valued. The adjusted replacement costs range from RMB5,070 per sq.m. to RMB5,130 per sq.m. for industrial buildings and from RMB8,300 per sq.m. to RMB9,500 per sq.m. for ancillary building based on our research of the local construction costs. The replacement cost adopted in the valuation is consistent with the findings of our research.

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VALUATION REPORT

VALUATION CERTIFICATE

Group II — Property interests held for development by the Group in the PRC

No.	Property	Description and tenure	Particulars of occupancy	Market value in existing state as at 30 November 2024
				<i>RMB</i>
2.	West of Fenglipu and south of Songbei Road, Suzhou Industrial Park, Suzhou City, Jiangsu Province, the PRC (中國江蘇省蘇州市蘇州工業園區鳳裡浦西、淞北路南)	The property comprises a parcel of land with a site area of approximately 24,882.80 sq.m. which is being developed into an industrial office development with a total planned gross floor area of approximately 81,888.79 sq.m. (the “Development”). As at the Valuation Date, the property was under development and was scheduled to be completed in June 2026. Upon completion, the property will have a total planned gross floor area of approximately 81,888.79 sq.m. As advised by the Group, the total construction cost of the property was estimated to be approximately RMB439,082,568.81 of which RMB47,898,396.87 had been paid as at the Valuation Date. The Development is located in Suzhou Industrial Park, with approximately 11.2 km to Suzhou Industrial Park Railway Station and 52.0 km to Sunan Shuofang International Airport. The land use rights of the Development have been granted for a term expiring on 19 January 2053 for industrial use.	As at the Valuation Date, the property was under construction.	97,790,000 (100% interest attributable to the Group: 97,790,000)

Notes:

- Pursuant to State-owned Construction Land Use Right Transfer Contract (國有建設用地使用權出讓合同) — No. 3205032023CR0001 dated 16 January 2023 issued by the Suzhou Industrial Park Planning and Construction Committee (蘇州工業園區規劃建設委員會), the land use rights of a parcel of land with a site area of approximately 24,882.80 sq.m. have been granted to Vigonvita Life Sciences Co., Ltd. (蘇州旺山旺水生物醫藥股份有限公司, formerly known as 蘇州旺山旺水生物醫藥有限公司), the “Company”) for a term of 30 years for industrial use at a total land premium of approximately RMB55,800,000.

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As revealed from the aforesaid State-owned Construction Land Use Right Transfer Contract, the property is subject to the following material development conditions:

Permitted Use	:	Industrial (R&D)
Plot Ratio	:	≥ 3.5 and ≤ 4.0
Maximum Permitted Accountable	:	≥ 87,089.80 sq.m.
Gross Floor Area		
Site Coverage	:	≤ 40%
Height Restriction	:	≤ 100m
Greening Rate	:	≤ 20%
Building Covenant	:	To commence construction before 15 January 2024 and to complete construction before 15 January 2026
Other Material Restrictions	:	–

- Pursuant to a Real Estate Ownership Certificate (for land) — Su (2023) Su Zhou Gong Ye Yuan Qu Bu Dong Chan Quan Di No. 0000029 issued by the Suzhou Industrial Park Planning and Construction Committee (蘇州工業園區規劃建設委員會), the land use rights of the Development with a total site area of approximately 24,882.80 sq.m. have been granted to the Company, for a term expiring on 19 January 2053 for industrial use.
- Pursuant to a Construction Land Planning Permit — Di Zi Di No. 320599202300014, permission for the planning of a land parcel with a total site area of approximately 24,882.80 sq.m. has been granted to the Company.
- Pursuant to a Construction Works Planning Permit — Jian Zi Di No. 320599202300272 in favour of the Company, the construction work of the Development with a total gross floor area of approximately 82,223.85 sq.m. has been approved for construction.
- Pursuant to a Construction Work Commencement Permit — No. 320594202310200101 in favour of the Company, permission has been given by the relevant local authority to commence the construction work of the Development with a total gross floor area of approximately 81,888.79 sq.m.
- As advised by the Group, the details of the property are set out as below:

Classification	Usage	Gross Floor Area
		<i>(sq.m.)</i>
Group II – Property interests held for development by the Group in the PRC	Industrial	62,365.03
	Basement	19,523.76
	Total:	<u>51,955.11</u>

- We have been provided with the PRC Legal Opinion, which contains, inter alia, the following: –
 - The Company has legally and validly obtained the land use rights and the building ownership of the property under the terms of the Real Estate Ownership Certificates;
 - The Company has the right to freely occupy, use, lease, or dispose of the property; and
 - The land use rights of the property have been pledged to Suzhou Branch of Shanghai Pudong Development Bank Co., Ltd. (上海浦東發展銀行股份有限公司蘇州分行).
- Our valuation has been made on the following basis and analysis:

In our valuation of the land use rights, we have considered and analyzed 2 land sale comparables in the vicinity. The adjusted site values of the land sales range from RMB2,261 to RMB2,262 per sq.m. for industrial use. The unit rate adopted in the valuation is consistent with the unit rates of the relevant comparables after due adjustments in terms of location, time and size, etc.

Regarding the building portion, the current replacement cost of the building is assessed by determining the construction cost of a modern substitute building with the same service capacity as the building which is being valued. The adjusted replacement costs range from RMB5,070 per sq.m. to RMB5,130 per sq.m. for industrial buildings and from RMB6,130 per sq.m. to RMB6,620 per sq.m. for basement based on our research of the local construction costs. The replacement cost adopted in the valuation is consistent with the findings of our research.

APPENDIX IV

TAXATION AND FOREIGN EXCHANGE

TAXATION FOR HOLDERS OF SECURITIES

Income tax and capital gains tax of holders of the H Shares is subject to the laws and practices of the PRC and of jurisdictions in which holders of H Shares are residents or otherwise subject to tax. The following summary of certain relevant taxation provisions is based on current laws and practices, and has not taken in to account the expected change or amendment to the relevant laws and policies and does not constitute any opinion or advice. The discussion does not deal with all possible tax consequences relating to an investment in the H shares, nor does it take into account the specific circumstances of any particular investor, some of which may be subject to special regulation. Accordingly, you should consult your own tax adviser regarding the tax consequences of an investment in the H shares. The discussion is based upon laws and relevant interpretations in effect as of the Latest Practicable Date, all of which are subject to change and may have retrospective effect.

No issues on PRC or Hong Kong taxation other than income tax, capital gain tax and profits tax, business tax/VAT, stamp duty and estate duty were referred in the discussion. Prospective investors are urged to consult their financial advisors regarding the PRC, Hong Kong and other tax consequences of owning and disposing of the H Shares.

THE PRC TAXATION

Taxation on Dividends

Individual Investor

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》), which was most recently amended on August 31, 2018 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was most recently amended on December 18, 2018 (hereinafter collectively referred to as the “**IIT Law**”), dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by relevant tax treaty.

Pursuant to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (hereinafter referred to as the “**Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income** (《對所得避免雙重徵稅和防止偷漏稅的安排》)”) signed by the Mainland of China and the Hong Kong Special Administrative Region on August 21, 2006, the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total amount of dividends payable. If a Hong Kong resident directly holds 25% or more of equity interest in a PRC company and the Hong Kong resident is the beneficial owner of the dividends and meets other

APPENDIX IV

TAXATION AND FOREIGN EXCHANGE

conditions, such tax shall not exceed 5% of the total amount of dividends payable by the PRC company. The Fifth Protocol to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income (《國家稅務總局關於〈內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排〉第五議定書》) (the “**Fifth Protocol** (《第五協議書》)”) issued by the SAT and became effective on December 31, 2019 provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

Enterprise Investors

In accordance with the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) issued by NPC on March 16, 2007 and latest amended on December 29, 2018 and the Implementation Provisions of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) issued by the State Council on December 6, 2007, came into effect on January 1, 2008 and amended on April 23, 2019 (hereinafter collectively referred to as the “**EIT Law**”), a non-resident enterprise is generally subject to a 10% enterprise income tax on PRC-sourced income (including dividends received from a PRC resident enterprise), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise. Such withholding tax may be reduced or exempted pursuant to an applicable treaty for the avoidance of double taxation.

The Circular of the State Administration of Tax on Issues Relating to the Withholding and Remitting of Enterprise Income Tax by PRC Resident Enterprises on Dividends Distributed to Overseas Non-Resident Enterprise Shareholders of H Shares (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》), which was issued and implemented by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold corporate income tax at a rate of 10% on the dividends paid to non-PRC resident enterprise holders of H Shares which are derived out of profit generated since 2008. Non-PRC resident enterprise shareholders who need to enjoy tax treaty benefits, the relevant provisions of such tax treaty shall apply.

Pursuant to the Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安排》), the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total amount of dividends payable. If a Hong Kong resident directly holds 25% or more of equity interest in a PRC company and the Hong Kong resident is the beneficial owner of the dividends and meets other conditions, such tax shall not exceed 5% of the total amount of dividends payable by the PRC company. The Fifth Protocol (《第五協議書》) provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

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Although there may be other provisions under the Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安排》), the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》).

Tax Treaties

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC might be entitled to a reduction of the Chinese corporate income tax imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the corporate income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

Taxation on Share Transfer

VAT and Local Additional Tax

Pursuant to the Notice on Fully Implementing the Pilot Reform for the Transition from Business Tax to Value-added Tax (《關於全面推開營業稅改徵增值稅試點的通知》) (the “**Circular 36**”), which was implemented on May 1, 2016, partially abolished on July 1, 2017, January 1, 2018 and April 1, 2019, and partially amended on July 1, 2017 and March 20, 2019, entities and individuals engaged in the services sale in the PRC are subject to VAT and “engaged in the services sale in the PRC” means that the seller or buyer of the taxable services is located in the PRC. Circular 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable revenue (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals who transfer financial products are exempt from VAT, which is also provided in the Notice of Ministry of Finance and State Administration of Taxation on Several Tax Exemption Policies for Business Tax on Sale and Purchase of Financial Commodities by Individuals (《財政部、國家稅務總局關於個人金融商品買賣等營業稅若干免稅政策的通知》) effective on January 1, 2009. According to these regulations, if the holder is a non-resident individual, the PRC VAT is exempted from the sale or disposal of H shares; if the holder is a non-resident enterprise and the H-share buyer is an individual or entity located outside the PRC, the holder is not necessarily required to pay the PRC VAT, but if the H-share buyer is an individual or entity located in China, the holder may be required to pay the PRC VAT.

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However, in view of no clear regulations, it is still uncertain whether the non-Chinese resident enterprises are required to pay the PRC VAT for the disposal of H shares in practice.

At the same time, VAT payers are also required to pay urban maintenance and construction tax, education surtax and local education surcharge, which shall be usually subject to 12% of the VAT payable (if any).

Income Tax

Individual Investors

According to the IIT Law, gains on the transfer of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular on Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the SAT on March 30, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. The SAT has not expressly stated whether it will continue to exempt tax on income of individuals from transfer of the shares of listed enterprises in the latest amended IIT Law.

However, on December 31, 2009, the Ministry of Finance, SAT and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》), which came into effect on January 1, 2010, which states that individuals' income from the transfer of listed shares obtained from the public offering of listed companies and transfer market on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) jointly issued and implemented by such departments on November 10, 2010). As of the Latest Practicable Date, no aforesaid provisions have expressly provided that individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges.

Enterprise Investors

In accordance with the EIT Law, a non-resident enterprise is generally subject to corporate income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income

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tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Stamp Duty

According to the Stamp Duty Law of the PRC (《中華人民共和國印花稅法》), which was promulgated on June 10, 2021 and came into effect on July 1, 2022, PRC stamp duty only applies to specific taxable document executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the date of this document, no estate duty has been levied in the PRC under the PRC laws.

EIT

According to the EIT Law, enterprises and other income-generating organizations (hereinafter collectively referred to as “an enterprise” or “enterprises”) within the territory of the PRC are the taxpayers of enterprise income tax and shall pay enterprise income tax in accordance with the provisions of the EIT Law. The Enterprise Income Tax rate is 25%.

According to the Administrative Measures for Determination of High and New Tech Enterprises (《高新技術企業認定管理辦法》), which was promulgated by the Ministry of Science and Technology, the Ministry of Finance and the State Administration of Taxation on April 14, 2008, amended on January 29, 2016 and became effective on January 1, 2016, an enterprise recognized as a high and new technology enterprise may apply for a preferential enterprise income tax rate of 15% pursuant to the relevant requirements of the EIT Law.

VAT

Pursuant to the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the MOF, came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation

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is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the SAT issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer's VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the SAT and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

On December 25, 2024, the SCNPC promulgated the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》), which will become effective on January 1, 2026, and the Interim Regulations of the PRC on Value-Added Tax will be abolished.

TAXATION IN HONG KONG

Tax on Dividends

Under the current practice of the Inland Revenue Department of Hong Kong, no tax is payable in Hong Kong in respect of dividends paid by us.

Capital Gains Tax and Profit Tax

No tax is imposed in Hong Kong in respect of capital gains from the sale of H Shares. However, trading gains from the sale of the H Shares by persons carrying on a trade, profession or business in Hong Kong, where such gains are derived from or arise in Hong Kong from such trade, profession or business will be subject to Hong Kong profits tax, which is currently imposed at the maximum rate of 16.5% on corporations and at the maximum rate of 15% on unincorporated businesses. Certain categories of taxpayers (for example, financial institutions, insurance companies and securities dealers) are likely to be regarded as deriving trading gains rather than capital gains unless these taxpayers can prove that the investment securities are held for long-term investment purposes. Trading gains from sales of H Shares effected on the Hong Kong Stock Exchange will be considered to be derived from or arise in Hong Kong. Liability for Hong Kong profits tax would thus arise in respect of trading gains from sales of H Shares effected on the Hong Kong Stock Exchange realized by persons carrying on a business of trading or dealing in securities in Hong Kong.

Stamp Duty

Hong Kong stamp duty, currently charged at the ad valorem rate of 0.1% on the higher of the consideration for or the market value of the H Shares, will be payable by the purchaser on every purchase and by the seller on every sale of Hong Kong securities, including H Shares (in other words, a total of 0.2% is currently payable on a typical sale and purchase transaction involving H Shares). In addition, a fixed duty of HK\$5.00 is currently payable on any

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instrument of transfer of H Shares. Where one of the parties is a resident outside Hong Kong and does not pay the ad valorem duty due by it, the duty not paid will be assessed on the instrument of transfer (if any) and will be payable by the transferee. If no stamp duty is paid on or before the due date, a penalty of up to ten times the duty payable may be imposed.

Estate Duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

FOREIGN EXCHANGE ADMINISTRATION IN THE PRC

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and cannot be freely converted into foreign currency. The SAFE, with the authorization of the People's Bank of China (the "PBOC"), is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

The Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which was issued by the State Council on January 29, 1996, implemented on April 1, 1996 and latest amended on August 5, 2008, classifies all international payments and transfers into current items and capital items. Current items are subject to the reasonable examination of the veracity of transaction documents and the consistency of the transaction documents and the foreign exchange receipts and payments by financial institutions engaging in conversion and sale of foreign currencies and supervision and inspection by the foreign exchange control authorities. For capital items, overseas organizations and overseas individuals making direct investments in the PRC shall, upon approval by the relevant authorities in charge, process registration formalities with the foreign exchange control authorities. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and foreign exchange settlement funds under the capital account are required to be used only for purposes as approved by the competent authorities and foreign exchange administrative authorities. In the event that international revenues and expenditure occur or may occur a material imbalance, or the national economy encounters or may encounter a severe crisis, the State may adopt necessary safeguard and control measures on international revenues and expenditure.

The Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》), which was promulgated by the PBOC on June 20, 1996 and implemented on July 1, 1996, removes other restrictions on convertibility of foreign exchange under current items, while imposing existing restrictions on foreign exchange transactions under capital account items.

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According to the Announcement on Improving the Reform of the Renminbi Exchange Rate Formation Mechanism (《關於完善人民幣匯率形成機制改革的公告》), which was issued by the PBOC and implemented on July 21, 2005, the PRC has started to implement a managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand and adjusted with reference to a basket of currencies since July 21, 2005. Therefore, the Renminbi exchange rate was no longer pegged to the U.S. dollar. PBOC would publish the closing price of the exchange rate of the Renminbi against trading currencies such as the U.S. dollar in the interbank foreign exchange market after the closing of the market on each working day, as the central parity of the currency against Renminbi transactions on the following working day.

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for current item transactions may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at the designated foreign exchange bank, on the strength of valid transaction receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange (such as our Company) may, on the strength of resolutions of the board of directors or the shareholders' meeting on the distribution of profits, effect payment from foreign exchange accounts at the designated foreign exchange bank, or effect exchange and payment at the designated foreign exchange bank.

According to the Decisions on Matters including Canceling and Adjusting a Batch of Administrative Approval Items (《國務院關於取消和調整一批行政審批項目等事項的決定》) which was promulgated by the State Council on October 23, 2014, it decided to cancel the approval requirement of the SAFE and its branches for the remittance and settlement of the proceeds raised from the overseas listing of the foreign shares into RMB domestic accounts.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE and implemented on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionizing and Regulating Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) which was promulgated by the SAFE and implemented on June 9, 2016 and revised on December 4, 2023, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions.

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PRC LEGAL SYSTEM

The PRC legal system is based on the Constitution of the PRC (《中華人民共和國憲法》) (the “**Constitution**”) and is made up of written laws, administrative regulations, local regulations, separate regulations, autonomous regulations, rules and regulations of departments, rules and regulations of local governments, international treaties of which the PRC government is a signatory, and other regulatory documents. Court verdicts do not constitute binding precedents. However, they may be used as judicial reference and guidance.

According to the Constitution and the Legislation Law of the PRC (2015 revision) (《中華人民共和國立法法(2015年修訂)》) (the “**Legislation Law**”), the NPC and the SCNPC are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing civil and criminal matters, state organs and other matters. The SCNPC is empowered to formulate and amend laws other than those required to be enacted by the NPC and to supplement and amend any parts of laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of the PRC administration and has the power to formulate administrative regulations based on the Constitution and laws.

The people’s congresses of provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual requirements of their own respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations.

The ministries and commissions of the State Council, PBOC, National Audit Office of the PRC as well as the other organs endowed with administrative functions directly under the State Council may, in accordance with the laws as well as the administrative regulations, decisions and orders of the State Council and within the limits of their power, formulate rules.

The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations in terms of urban and rural development and management, environmental protection, and historical and cultural protection based on the specific circumstances and actual requirements of such cities, which will become enforceable after being reported to and approved by the standing committees of the people’s congresses of the relevant provinces or autonomous regions but such local regulations shall conform with the Constitution, laws, administrative regulations, and the relevant local regulations of the relevant provinces or autonomous regions. People’s congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the nationality (nationalities) in the areas concerned.

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The people's governments of the provinces, autonomous regions, and municipalities directly under the central government and the cities divided into districts or autonomous prefectures may enact rules, in accordance with laws, administrative regulations and the local regulations of their respective provinces, autonomous regions or municipalities. The Constitution has supreme legal authority and no laws, administrative regulations, local regulations, autonomous regulations or separate regulations may contravene the Constitution. The authority of laws is greater than that of administrative regulations, local regulations and rules. The authority of administrative regulations is greater than that of local regulations and rules. The authority of local regulations is greater than that of the rules of the local governments at or below the corresponding level. The authority of the rules enacted by the people's governments of the provinces or autonomous regions is greater than that of the rules enacted by the people's governments of the city divided into districts or autonomous prefecture within the administrative areas of the provinces and the autonomous regions.

The NPC has the power to alter or annul any inappropriate laws enacted by the SCNPC, and to annul any autonomous regulations or separate regulations which have been approved by the SCNPC but which contravene the Constitution or the Legislation Law. The SCNPC has the power to annul any administrative regulations that contravene the Constitution and laws, to annul any local regulations that contravene the Constitution, laws or administrative regulations, and to annul any autonomous regulations or local regulations which have been approved by the standing committees of the people's congresses of the relevant provinces, autonomous regions or municipalities directly under the central government, but which contravene the Constitution and the Legislation Law. The State Council has the power to alter or annul any inappropriate ministerial rules and rules of local governments. The people's congresses of provinces, autonomous regions or municipalities directly under the central government have the power to alter or annul any inappropriate local regulations enacted or approved by their respective standing committees. The people's governments of provinces and autonomous regions have the power to alter or annul any inappropriate rules enacted by the people's governments at a lower level.

According to the Constitution and the Legislation Law, the power to interpret laws is vested in the SCNPC. According to the Decision of the Standing Committee of the NPC Regarding the Strengthening of Interpretation of Laws (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, the Supreme People's Court of the PRC (the "**Supreme People's Court**") has the power to give general interpretation on questions involving the specific application of laws and decrees in court trials. The State Council and its ministries and commissions are also vested with the power to give interpretation of the administrative regulations and department rules which they have promulgated. At the regional level, the power to give interpretations of the local laws and regulations as well as administrative rules is vested in the regional legislative and administrative organs which promulgate such laws, regulations and rules.

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PRC JUDICIAL SYSTEM

Under the Constitution and the PRC Law on the Organization of the People’s Courts (2018 revision) (《中華人民共和國法院組織法(2018年修訂)》), the PRC judicial system is made up of the Supreme People’s Court, the local people’s courts and special people’s courts.

The local people’s courts are comprised of the primary people’s courts, the intermediate people’s courts and the higher people’s courts. The higher level people’s courts supervise the primary and intermediate people’s courts. The people’s procuratorates also have the right to exercise legal supervision over the civil proceedings of people’s courts of the same level and lower levels. The Supreme People’s Court is the highest judicial body in the PRC. It supervises the judicial administration of the people’s courts at all levels.

The PRC Civil Procedure Law (2023 revision) (《中華人民共和國民事訴訟法(2023年修訂)》) (the “**Civil Procedure Law**”), which was adopted in 1991 and amended in 2007, 2012, 2017, 2021 and 2023, sets forth the criteria for instituting a civil action, the jurisdiction of the people’s courts, the procedures to be followed for conducting a civil action and the procedures for enforcement of a civil judgment or order. All parties to a civil action conducted within the PRC must comply with the Civil Procedure Law. Generally, a civil case is initially heard by a local court of the municipality or province in which the defendant resides. The parties to a contract may, by express agreement, select a judicial court where civil actions may be brought, provided that the judicial court is either the plaintiff’s or the defendant’s domicile, the place of execution or implementation of the contract or the place of the object of the action, provided that such choice shall not violate the requirements of the level of jurisdiction and exclusive jurisdiction.

A foreign national or enterprise generally has the same litigation rights and obligations as a citizen or legal person of the PRC. If a foreign country’s judicial system limits the litigation rights of PRC citizens and enterprises, the PRC courts may apply the same limitations to the citizens and enterprises of that foreign country within the PRC.

If any party to a civil action refuses to comply with a judgment or ruling made by a people’s court or an award made by an arbitration panel in the PRC, the other party may apply to the people’s court for the enforcement of the same. There are time limits of two years imposed on the right to apply for such enforcement. If a person fails to satisfy a judgment made by the court within the stipulated time, the court will, upon application by either party, enforce the judgment in accordance with the law.

A party seeking to enforce a judgment or ruling of a people’s court against a party who is not personally or whose property is not within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of the judgment or ruling. A foreign judgment or ruling may also be recognized and enforced by the people’s court according to PRC enforcement procedures if the PRC has entered into or acceded to an international treaty with the relevant foreign country, which provides for such recognition and enforcement, or if the judgment or ruling satisfies the court’s examination according to the principle of reciprocity, unless the people’s court finds that the recognition or enforcement of such judgment or ruling will result in a violation of the basic legal principles of the PRC, its sovereignty or security or against social and public interest.

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According to the Arrangement on Mutual Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland China and of the Hong Kong Special Administrative Region Pursuant to Agreed Jurisdiction by Parties Concerned (《最高人民法院關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) promulgated by the Supreme People’s Court on July 3, 2008 and implemented on August 1, 2008, in the case of final judgment, defined with payment amount and enforcement power, made between the court of China and the court of the Hong Kong Special Administrative Region in a civil and commercial case with written jurisdiction agreement, any party concerned may apply to the People’s Court of China or the court of the Hong Kong Special Administrative Region for recognition and enforcement based on this arrangement. “Choice of court agreement in written” refers to a written agreement defining the exclusive jurisdiction of either the People’s Court of China or the court of the Hong Kong Special Administrative Region in order to resolve dispute with particular legal relation occurred or likely to occur by the party concerned. Therefore, the party concerned may apply to the Court of China or the court of the Hong Kong Special Administrative Region to recognize and enforce the final judgment made in China or Hong Kong that meet certain conditions of the aforementioned regulations.

THE COMPANY LAW, THE OVERSEAS LISTING TRIAL MEASURES AND THE GUIDELINES

A joint stock limited company which was incorporated in the PRC and seeking a listing on the HKSE is mainly subject to the following three laws and regulations in the PRC:

The Company Law of the PRC (《中華人民共和國公司法》) (the “**Company Law**”) which was promulgated by the Standing Committee of the NPC on December 29, 1993, came into effect on July 1, 1994, revised on December 25, 1999, August 28, 2004, October 27, 2005 and December 28, 2013, October 26, 2018, December 29, 2023 respectively and the latest revision of which was implemented on July 1, 2024.

The Overseas Listing Trial Measures which were promulgated by the CSRC on February 17, 2023 and came into effect on March 31, 2023, and were applicable to the overseas offering and listing of PRC domestic companies’ securities.

The Guidelines for Articles of Association of Listed Companies (《上市公司章程指引》) (the “**Guidelines**”) which were issued by the CSRC on December 16, 1997, latest revised on December 15, 2023 and came into effect on the same date, providing the guidelines for the Articles of Association. As such, the contents provided in the Guidelines are set out in the Articles of Association of the Company, the summary of which is set out in the section entitled “Appendix V — Summary of Articles of Association” in this document.

Set out below is a summary of the major provisions of the Company Law, the Overseas Listing Trial Measures and the Guidelines applicable to the Company.

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General

A joint stock limited company refers to an enterprise legal person incorporated in accordance with the Company Law with its registered capital divided into shares of equal par value. The liability of its shareholders is limited to the amount of shares held by them and the company is liable to its creditors for an amount equal to the total value of its assets.

A joint stock limited company shall conduct its business in accordance with laws and administrative regulations. It may invest in other limited liability companies and joint stock limited companies and its liabilities with respect to such invested companies are limited to the amount invested. Unless otherwise provided by laws, the joint stock limited company may not be a contributor that undertakes joint and several liabilities for the debts of the invested companies.

Incorporation

A joint stock limited company may be incorporated by promotion or public subscription.

A joint stock limited company may be incorporated by a minimum of two but not more than 200 promoters, and at least half of the promoters must have residence within the PRC.

The promoters of a joint stock limited company incorporated by public subscription must convene an inaugural meeting within 30 days after the issued shares have been fully paid up, and must give notice to all subscribers or make an announcement of the date of the inaugural meeting 15 days before the meeting. The inaugural meeting may be convened only with the presence of subscribers representing at least half of the voting rights in the company. The convening and voting procedures of the inaugural meeting of a joint stock company incorporated by promotion shall be stipulated in articles of association of the company or in the agreement of the promoters. At the inaugural meeting, matters including the adoption of articles of association and the election of directors and supervisors of the company will be dealt with. All resolutions of the meeting require the approval of subscribers with more than half of the voting rights present at the meeting.

Within 30 days after the conclusion of the inaugural meeting, the board of directors must authorize representatives to apply to the registration authority for registration of the establishment of the joint stock limited company. A company is formally established, and has the status of a legal person, after the business license has been issued by the relevant registration authority.

A joint stock limited company’s promoters shall be liable for: (i) the payment of all expenses and debts incurred in the incorporation process jointly and severally if the company cannot be incorporated; (ii) the refund of subscription monies to the subscribers, together with interest, at bank rates for a deposit of the same term jointly and severally if the company cannot be incorporated; and (iii) damages suffered by the company as a result of the default of the promoters in the course of incorporation of the company. According to the Interim Provisional Regulations on the Administration of Share Issuance and Trading (《股票發行與交易管理暫行

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條例》) promulgated by the State Council on April 22, 1993 (which is only applicable to the issuance and trading of shares in the PRC and their related activities), if a company is established by means of public subscription, the promoters of such company are required to sign on the document to ensure that the document does not contain any misrepresentation, serious misleading statements or material omissions, and assume joint and several responsibility for it.

Registered Capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any over-valuation or under-valuation. The share issued by a company must be registered share.

Shares held by shareholders of a joint stock limited company may be transferred to other shareholders or to persons other than the shareholders; if articles of association of the company impose restrictions on the transfer of shares, such transfer shall be conducted in accordance with the provisions of articles of association. The transfer of shares by shareholders should be conducted via the legally established stock exchange or in accordance with other methods as stipulated by the State Council. Transfer of shares by a shareholder must be made by means of an endorsement or by other means stipulated by laws or administrative regulations.

Shares issued by a company prior to the public offer of its shares shall not be transferred within one year from the date of listing of the shares of the company on a stock exchange. If there are other provisions stipulated by laws, administrative regulations or the securities regulatory authorities under the State Council on the transfer of shares held by shareholders or beneficial owners of a listed company, such provisions shall apply accordingly. Directors, supervisors and senior management of a company shall not transfer over 25% of the shares held by each of them in the company each year during their term of office determined at the time of appointment and shall not transfer any share of the company held by each of them within one year after the listing date. There is no restriction under the Company Law as to the percentage of shareholding a single shareholder may hold in a company.

Increase of Registered Capital and Issue of Shares

According to the Company Law, in the event a company proposes to issue new shares, resolutions shall be passed at general meeting in accordance with the articles of association to determine the class, amount and issue price of the new shares. All issue of shares of a joint stock limited company shall be based on the principles of equality and fairness. The same class of shares must carry equal rights. Shares issued at the same time and within the same class must be issued on the same conditions and at the same price. It may issue shares at par value or at a premium, but it may not issue shares below the par value.

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A company may issue the following classified shares with rights different from those of common shares in accordance with its articles of incorporation: (i) Shares with preferential or inferior distribution of profits or surplus property; (ii) Shares with more or less voting rights per share than common shares; (iii) Shares the transfer of which is subject to restrictions such as the consent of the Company; (iv) Other classes of shares as prescribed by the State Council. A company that makes a public offering of its shares shall not issue the classified shares set in (ii) and (iii), except those that have already been issued prior to the public offering.

After the new share issuance has been paid up, the change shall be registered with the company registration authorities and an announcement shall be made.

According to the Company Law, when the company issues shares in registered form, it shall maintain a register of shareholders, stating the following matters:

- the name and domicile of each shareholder;
- the class and amount of shares held by each shareholder;
- the serial numbers of shares held by each shareholder if issued in paper form; and
- the date on which each shareholder acquired the shares.

Reduction of Registered Capital

A company may reduce its registered capital in accordance with the following procedures prescribed by the Company Law:

- the company shall prepare a balance sheet and an inventory of the assets;
- the reduction of registered capital shall be approved by a general meeting;
- the company shall inform its creditors of the reduction in registered capital within 10 days and publish an announcement of the reduction in the newspaper or the National Enterprise Credit Information Publicity System within 30 days after the resolution approving the reduction has been passed;
- creditors shall within 30 days after receiving the notice, or within 45 days of the public announcement if no notice has been received, require the company to pay its debts or provide corresponding guarantees covering the debts;
- the company shall apply to the relevant administration of registration for the registration of the reduction in registered capital.

Unless otherwise provided by law or stipulated in articles of association of the joint stock limited company, a company shall reduce its registered capital in accordance with the proportion of shareholders' share.

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Repurchase of Shares

According to the Company Law, a joint stock limited company may not purchase its shares other than for one of the following purposes: (i) to reduce its registered capital; (ii) to merge with another company that holds its shares; (iii) to grant its shares for carrying out an employee stock ownership plan or equity incentive plan; (iv) to purchase its shares from shareholders who vote against the resolution regarding the merger or division with other companies at a general meeting; (v) to apply shares for conversion of convertible corporate bonds issued by a listed company; and (vi) to maintain the company value and protect the shareholders' interests of a listed company as necessary.

Repurchase of its own shares on the grounds set out in (i) and (ii) above shall be subject to resolution passed by the general meeting; repurchase of its own shares on the grounds set out in (iii), (v) or (vi) above shall be subject to a resolution of the company's board of directors shall be made by a two-third majority of directors attending the meeting in accordance with the provisions of the company's articles of association or as authorized by the general meeting.

Following the repurchase of its own shares in accordance with (i) above, such shares shall be canceled within 10 days from the date of repurchase; the shares shall be transferred or canceled within six months if the repurchase of its own shares is in accordance with either (ii) or (iv) above; and the shares repurchased in accordance with (iii), (v) or (vi) above shall not exceed 10% of the company's total issued shares, and shall be transferred or canceled within three years.

A listed company shall perform its obligation of information disclosure according to the provisions of the Securities Law when repurchasing its own shares. In the event the repurchase of its own shares is in accordance with (iii), (v) or (vi) above, centralized public trading shall be adopted.

A company shall not accept its own shares as the subject matter of a mortgage.

Transfer of Shares

Shares held by shareholders may be transferred in accordance with the relevant laws and regulations. Pursuant to the Company Law, transfer of shares by shareholders shall be carried out at a legally established securities exchange or in other ways stipulated by the State Council. No modifications of registration in the share register shall be carried out within 20 days prior to the convening of a general meeting or 5 days prior to the base date for determination of dividend distributions. However, where there are separate provisions by laws, administrative regulations or the securities regulatory authority of the State Council on alternation of registration in the share register of listed companies, those provisions shall prevail.

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According to the Company law, shares issued prior to the public issuance of shares shall not be transferred within one year from the date of the joint stock limited company's listing on a stock exchange. Directors, supervisors and the senior management shall declare to the company their shareholdings in the company and any changes of such shareholdings; they shall not transfer more than 25% of all the shares they hold in the company each year during their term of office determined at the time of appointment and shall not transfer the shares they hold within one year from the date on which the company's shares are listed and commenced trading on a stock exchange, nor within six months after their resignation from their positions with the company.

Shareholders

According to the Company Law and the Guidelines, the rights of holders of ordinary shares of a joint stock limited company include:

- the right to attend or appoint a proxy to attend general meetings and to vote thereat;
- the right to transfer shares in accordance with laws, administrative regulations and provisions of the articles of association;
- the right to inspect the company's articles of association, share register, counterfoil of company debentures, minutes of general meetings, resolutions of meetings of the board of directors, resolutions of meetings of the board of supervisors and financial and accounting reports and to make proposals or enquiries on the company's operations;
- the right to bring an action in the people's court to rescind resolutions passed by general meetings and board of directors where the articles of association is violated by the above resolutions;
- the right to receive dividends and other types of interest distributed in proportion to the number of shares held;
- in the event of the termination or liquidation of the company, the right to participate in the distribution of residual properties of the company in proportion to the number of shares held; and
- other rights granted by laws, administrative regulations, other regulatory documents and the company's articles of association.

The obligations of a shareholder include the obligation to abide by the Company's articles of association, to pay the subscription moneys in respect of the shares subscribed for and in accordance with the form of making capital contributions, to be liable for the company's debts and liabilities to the extent of the amount of his or her subscribed shares and any other shareholders' obligation specified in the company's articles of association.

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General Meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the Company Law. According to the Company Law, the general meeting exercises the following principal powers:

- to elect or remove the directors and supervisors and to decide on matters relating to the remuneration of directors and supervisors;
- to examine and approve reports of the board of directors;
- to examine and approve reports of the board of supervisors;
- to examine and approve the company's proposals for profit distribution plans and loss recovery plans;
- to decide on any increase or reduction of the company's registered capital;
- to decide on the issue of bonds by the company;
- to decide on issues such as merger, division, dissolution and liquidation of the company and other matters;
- to amend the company's articles of association; and
- other powers as provided for in the articles of association.

The general meeting may authorize the board of directors to make resolutions on the issue of bonds.

Annual general meeting is required to be held once every year. Extraordinary general meeting is required to be held within two months after the occurrence of any of the following:

- the number of directors is less than the number stipulated by the law or less than two thirds of the number specified in the articles of association;
- the aggregate losses of the company which are not recovered reach one-third of the company's total paid-in registered capital;
- when shareholders individually or in aggregate holding 10% or more of the company's shares request the convening of an extraordinary general meeting;
- whenever the board of directors deems necessary;
- when the board of supervisors so requests; or
- other circumstances as provided for in the articles of associations

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According to the Company Law, general meetings shall be convened by the board of directors, and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or does not perform his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or not performing his duties, a director nominated by more than half of directors shall preside over the meeting.

Where the board of directors is incapable of performing or not performing its duties of convening the general meeting, the board of supervisors shall convene and preside over such meeting in a timely manner. In case the board of supervisors fails to convene and preside over such meeting, shareholders alone or in aggregate holding more than 10% of the company's shares for 90 days consecutively may unilaterally convene and preside over such meeting.

According the Company Law, notice of annual general meeting shall state the time and venue of and matters to be considered at the meeting and shall be given to all shareholders 20 days before the meeting. Notice of extraordinary general meetings shall be given to all shareholders 15 days prior to the meeting.

There is no specific provision in the Company Law regarding the number of shareholders constituting a quorum in a general meeting.

According to the Company Law, shareholders except shareholders of classified shares present at general meeting have one vote for each share they hold, save that shares held by the company are not entitled to any voting rights.

Pursuant to the provisions of the articles of association or a resolution of the general meeting, the accumulative voting system may be adopted for the election of directors and supervisors at the general meeting. Under the accumulative voting system, each share shall be entitled to vote equivalent to the number of directors or supervisors to be elected at the general meeting and shareholders may consolidate their voting rights when casting a vote.

Pursuant to the Company Law, resolutions of the general meeting shall be adopted by more than half of the voting rights held by the shareholders present at the meeting. However, resolutions of the general meeting regarding the following matters shall be adopted by more than two-thirds of the voting rights held by the shareholders present at the meeting: (i) amendments to the articles of association; (ii) the increase or decrease of registered capital; (iii) the issue of any types of shares, warrants or other similar securities; (iv) the issue of debentures; (v) the merger, division, dissolution, liquidation or change in the form of the company; (vi) other matters considered by the general meeting, by way of an ordinary resolution, to be of a nature which may have a material impact on the company and should be adopted by a special resolution.

According to the Company Law, meeting minutes shall be prepared in respect of decisions on matters discussed at the general meeting. The chairman of the meeting and directors attending the meeting shall sign to endorse such minutes. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

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Board

According to the Company Law, a joint stock limited company other than that of small scale or with a limited number of shareholders which may not have a board of directors, shall have a board of directors, which shall consist of 3 or more members. Members of the board of directors may include representatives of the employees of the company, who shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. A joint stock limited company with more than 300 employees shall have employee representatives on its board of directors, unless a board of supervisors has been established pursuant to the law and contains employee representatives. The term of a director shall be stipulated in the articles of association, but no term of office shall last for more than three years. Directors may serve consecutive terms if re-elected. A director shall continue to perform his duties in accordance with the laws, administrative regulations and articles of association until a duly re-elected director takes office, if re-election is not conducted in a timely manner upon the expiry of his term of office, or if the resignation of directors results in the number of directors being less than the quorum. If a director resigns, the director shall notify the company in writing, and the resignation shall take effect on the date of receipt of the notification by the company, provided that the director shall continue to perform his duties if the circumstances stipulated in the preceding sentence exist.

The general meeting may resolve to terminate the appointment of a director, and the termination shall take effect on the date the resolution is made. If a director is dismissed before the expiration of the term of office without a valid reason, the director may request the company to compensate for the dismissal.

A joint stock limited company may, in accordance with the provisions of its articles of association, establish an audit committee consisting of directors on its board of directors, exercising the powers and functions of the board of supervisors as provided for in the Company Law, instead of having a board of supervisors or supervisors. The audit committee shall consist of three or more members, and a majority of the members shall not hold positions in the company other than that of director and shall not have any relationship with the company that may affect their independent and objective judgment. Employee representatives of the board of directors may be members of the audit committee. The company may set up other committees in the board of directors in accordance with the provisions of the articles of association.

According to the Company Law, the board of directors mainly exercises the following powers:

- to convene the general meetings and report on its work to the general meetings;
- to implement the resolutions passed in general meetings;
- to decide on the company's business plans and investment proposals;
- to formulate the company's profit distribution proposals and loss recovery proposals;

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- to formulate proposals for the increase or reduction of the company's registered capital and the issuance of corporate bonds;
- to prepare plans for the merger, division, dissolution and change in the form of the company;
- to formulate the company's basic management system; and
- to exercise any other power under the articles of association or granted by the general meeting.

Limitations on the powers of the board of directors in the articles of incorporation may not be imposed against a bona fide counterparty.

Board Meetings

According to the Company Law, meetings of the board of directors of a joint stock limited company shall be convened at least twice a year. Notice of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of voting rights, more than one-third of the directors or the board of supervisors. The chairman shall convene and preside over such meeting within 10 days after receiving such proposal. Meetings of the board of directors shall be held only if half or more of the directors are present. Resolutions of the board of directors shall be passed by more than half of all directors. Each director shall have one vote for resolutions to be approved by the board of directors. Directors shall attend board meetings in person. If a director is unable to attend a board meeting, he may appoint another director by a written power of attorney specifying the scope of the authorization to attend the meeting on his behalf.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director may be released from that liability.

Chairman of the Board

According to the Company Law, the board of directors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman are elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and examine the implementation of board resolutions. The vice chairman shall assist the work of the chairman. In the event that the chairman is incapable of performing or not performing his duties, the duties shall be performed by the vice chairman. In the event that the vice chairman is incapable of performing or not performing his duties, a director nominated by more than half of the directors shall perform his duties.

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Qualification of Directors

The Company Law provides that the following persons may not serve as a director:

- a person who is unable or has limited ability to undertake any civil liabilities;
- a person who has been convicted of an offense of bribery, corruption, embezzlement or misappropriation of property, or the destruction of socialist market economy order; or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence; in the case of a probation, less than two years have elapsed since the date of expiration of the probationary period;
- a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise;
- a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law and has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; or
- a person listed by the People's Court as dishonest judgment debtors, being liable for a relatively large amount of debts that are overdue.

Board of Supervisors

A joint stock limited company shall have a board of supervisors composed of not less than three members, unless it has an audit committee under the board of directors to exercise the powers of board of supervisors or it has a small scale or a limited number of shareholders which may not have a board of supervisors. The board of supervisors is made up of representatives of the shareholders and an appropriate proportion of representatives of the employees of the company. The actual proportion shall be stipulated in the articles of association, provided that the proportion of representatives of the employees shall not be less than one third of the supervisors. Representatives of the employees of the company in the board of supervisors shall be democratically elected by the employees at the employees' representative assembly, employees' general meeting or otherwise.

The directors and senior management may not act concurrently as supervisors.

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The board of supervisors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the board of supervisors are elected with approval of more than half of all the supervisors. The chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the chairman of the board of supervisors is incapable of performing or not performing his duties, the vice chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the vice chairman of the board of supervisors is incapable of performing or not performing his duties, a supervisor nominated by more than half of the supervisors shall convene and preside over the meetings of the board of supervisors.

Each term of office of a supervisor is three years and he or she may serve consecutive terms if re-elected. A supervisor shall continue to perform his duties in accordance with the laws, administrative regulations and articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his term of office, or if the resignation of supervisors results in the number of supervisors being less than the quorum.

The board of supervisors of a company shall hold at least one meeting every six months. According to the Company Law, a resolution of the board of supervisors shall be passed by more than half of all the supervisors, while according to the Opinions on Supplementary Amendment to Articles of Associations by Companies to be listed in Hong Kong (《關於到香港上市公司對公司章程作補充修改的意見的函》), a resolution of the board of supervisors shall be passed by more than two-thirds of all the supervisors.

The board of supervisors exercises the following powers:

- to review the company's financial position;
- to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or the resolutions of the general meeting;
- when the acts of directors and senior management are harmful to the company's interests, to require correction of those acts;
- to propose the convening of extraordinary general meetings and to convene and preside over general meetings when the board of directors fails to perform the duty of convening and presiding over general meeting under this law;
- to initiate proposals for resolutions to general meeting;
- to initiate proceedings against directors and senior management;
- other powers specified in the articles of association; and

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- Supervisors may attend board meetings and make enquiries or proposals in respect of board resolutions. The board of supervisors may initiate investigations into any irregularities identified in the operation of the company and, where necessary, may engage an accounting firm to assist their work at the company's expense.

Manager and Senior Management

According to the Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager shall report to the board of directors and may exercise the power in accordance with the provisions of the articles of association or the authorization of the board of directors. The manager shall attend board meetings.

According to the Company Law, senior management shall mean the manager, deputy manager(s), person-in-charge of finance, board secretary (in case of a listed company) of a company and other personnel as stipulated in the articles of association.

Duties of Directors, Supervisors and Senior Management

Directors, supervisors and senior management of the company are required in accordance with the Company Law to comply with the relevant laws, regulations and the articles of association, and have fiduciary and diligent duties to the company. Directors, supervisors and senior management are prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating of the company's properties. Directors and senior management are prohibited from:

- embezzlement of the company's property or misappropriation of the company's funds;
- depositing the company's funds into accounts under his own name or the name of other individuals;
- abusing their powers to accept any bribery or other illegal income;
- accepting and possessing commissions paid by a third party for transactions conducted with the company;
- unauthorized divulgence of confidential information of the company; or
- other acts in violation of their fiduciary duty to the company.

Without reporting to the board of directors or the general meeting and obtaining approval of the board of directors or the general meeting as required by the articles of association of the company, directors, supervisors and senior management shall not directly or indirectly enter into any contract or transaction with the company, take advantage of their positions to pursue business opportunities which otherwise are available to and could betaken by the company for

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the benefit of themselves or others, or operate a business similar to the business of the company they work for in favor of themselves or others. In voting for proposals for the aforementioned matters by the board of directors, interested directors shall not vote and their voting rights shall not be counted in the total valid votes. If the number of uninterested directors attending the meeting is less than three, relevant proposals shall be submitted to the general meeting for consideration.

Income generated by directors or senior management in violation of their duty of loyalty shall be returned to the company.

A director, supervisor or senior management who contravenes any law, regulation or the company's articles of association in the performance of his duties resulting in any loss to the company shall be personally liable to the company.

Finance and Accounting

According to the Company Law, a company shall establish financial and accounting systems in accordance with laws, administrative regulations and the regulations of the financial department of the State Council and shall at the end of each financial year prepare a financial and accounting report which shall be audited by an accounting firm as required by law. The company's financial and accounting report shall be prepared in accordance with provisions of the laws, administrative regulations and the regulations of the financial department of the State Council.

Pursuant to the Company Law, the company shall deliver its financial and accounting reports to all shareholders within the time limit stipulated in the articles of association and make its financial and accounting reports available at the company for inspection by the shareholders at least 20 days before the convening of an annual general meeting of shareholders. A company that makes public stock offerings shall publish its financial and accounting reports.

When distributing each year's after-tax profits, it shall set aside 10% of its after-tax profits into a statutory common reserve fund (except where the fund has reached 50% of its registered capital).

If its statutory common reserve fund is not sufficient to make up losses of the previous year, profits of the current year shall be applied to make up losses before allocation is made to the statutory common reserve fund pursuant to the above provisions.

After allocation of the statutory common reserve fund from after-tax profits, it may, upon a resolution passed at the general meeting, allocate discretionary common reserve fund from after-tax profits.

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The remaining after-tax profits after making up losses and allocation of common reserve fund shall be distributed in proportion to the number of shares held by the shareholders, unless otherwise stipulated in the articles of association.

Shares held by the Company shall not be entitled to any distribution of profit.

The premium received through issuance of shares at prices above par value and other incomes required by the financial department of the State Council to be allocated to the capital reserve fund shall be allocated to the company's capital reserve fund.

The Company's reserve fund shall be applied to make up losses of the company, expand its business operations or be converted to increase the registered capital of the company. Where reserves are used to cover loss of a company, the discretionary and statutory reserves shall be first used; if they are insufficient for covering loss, the capital reserve fund may be applied to make up the company's losses. Upon the conversion of statutory common reserve fund into capital, the balance of the statutory common reserve fund shall not be less than 25% of the registered capital of the company before such conversion.

The Company shall have no other accounting books except the statutory accounting books. Its assets shall not be deposited in any accounts opened in the name of any individual.

Appointment and Retirement of Accounting Firms

Pursuant to the Company Law, the appointment or dismissal of accounting firms responsible for the auditing of the company shall be determined by general meeting or board of directors or board of supervisors in accordance with provisions of articles of association. The accounting firm should be allowed to make representations when the general meeting or board of directors or board of supervisors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidences, books, financial and accounting reports and other accounting data to the accounting firm it employs without any refusal, withholding and misrepresentation.

Distribution of Profits

According to the Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve is drawn.

Amendments to Articles of Association

Any amendments to the company's articles of association must be made in accordance with the procedures set out in the company's articles of association. In relation to matters involving the company's registration, the amendment to articles of association shall be registered with the relevant authority in accordance with the applicable laws.

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Dissolution and Liquidation

According to the Company Law, a company shall be dissolved by reason of the following: (i) the term of its operations set down in the articles of association has expired or other events of dissolution specified in the articles of association have occurred; (ii) the general meeting resolve to dissolve the company; (iii) the company is dissolved by reason of merger or division; (iv) the business license is revoked; the company is ordered to close down or be dissolved; or (v) the company is dissolved by the people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all its shareholders, on the grounds that the company suffers significant hardship in its operation and management that cannot be resolved through other means, and the ongoing existence of the company would bring significant losses for shareholders. The company shall, within ten days of the occurrence of any of the aforementioned reasons for dissolution, disclose the reasons for dissolution on the National Enterprise Credit Information Publicity System.

In the event of (i) or (ii) above, if the property has not been distributed to the shareholders, a company may carry on its existence by amending its articles of association or passing a resolution at a general meeting. The amendment of the articles of association in accordance with provisions set out above shall require approval of more than two thirds of voting rights of shareholders attending a general meeting.

Where the company is dissolved in the circumstances described in subparagraphs (i), (ii), (iv), or (v) above, directors shall be the obligators of liquidation. A liquidation group shall be established and the liquidation process shall commence within 15 days after the occurrence of an event of dissolution.

The members of the company's liquidation group shall be composed of its directors or the personnel appointed by the general meeting. If a liquidation group is not established within the stipulated period, creditors may apply to the people's court and request the court to appoint relevant personnel to form the liquidation group. The people's court should accept such application and form a liquidation group to conduct liquidation in a timely manner.

The liquidation group shall consist of directors, unless the articles of association provide otherwise or the general meeting resolves to elect another person. If the liquidation obligor fails to fulfill its liquidation obligations in a timely manner and causes losses to the company or creditors, it shall be liable for compensation.

The liquidation group shall exercise the following powers during the liquidation period:

- to handle the company's assets and to prepare a balance sheet and an inventory of the assets;
- to notify creditors through notice or public announcement;
- to deal with the company's outstanding businesses related to liquidation;

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- to pay any tax overdue as well as tax amounts arising from the process of liquidation;
- to claim credits and pay off debts;
- to allocate the company's remaining assets after its debts have been paid off; and
- to represent the company in civil lawsuits.

The liquidation group shall notify the company's creditors within 10 days after its establishment and issue public notices in newspapers or on the National Enterprise Credit Information Publicity System within 60 days. A creditor shall lodge his claim with the liquidation group within 30 days after receiving notification, or within 45 days of the public notice if he did not receive any notification. A creditor shall state all matters relevant to his creditor rights in making his claim and furnish evidence. The liquidation group shall register such creditor rights. The liquidation group shall not make any debt settlement to creditors during the period of claim.

Upon liquidation of properties and the preparation of the balance sheet and inventory of assets, the liquidation group shall draw up a liquidation plan to be submitted to the general meeting or people's court for confirmation.

The company's remaining assets after payment of liquidation expenses, wages, social insurance expenses and statutory compensation, outstanding taxes and debts shall be distributed to shareholders according to their shareholding proportion. It shall continue to exist during the liquidation period, although it can only engage in any operating activities that are related to the liquidation. The company's properties shall not be distributed to the shareholders before repayments are made in accordance to the foregoing provisions.

Upon liquidation of the company's properties and the preparation of the balance sheet and inventory of assets, if the liquidation group becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to the people's court for bankruptcy liquidation. Following the acceptance of the bankruptcy application by the people's court, the liquidation group shall hand over all matters relating to the liquidation to the bankruptcy administrator designated by the people's court.

Upon completion of the liquidation, the liquidation group shall submit a liquidation report to the general meeting or the people's court for verification. Thereafter, the report shall be submitted to the registration authority of the company in order to cancel the company's registration, and a public notice of its termination shall be issued. Members of the liquidation group are required to discharge their duties honestly and in compliance with the relevant laws. Members of the liquidation group shall be prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating the company's properties.

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A member of the liquidation group is liable to indemnify the company and its creditors in respect of any loss arising from his intentional or gross negligence.

Where a company has not incurred any debt during its existence or has paid off all the debts, the registration of the company may be cancelled through the simplified procedure in accordance with the applicable provisions upon undertaking by all the shareholders.

The cancellation of registration of a company through the simplified procedure shall be announced through the National Enterprise Credit Information Publicity System, and the period of announcement may not be less than 20 days. If there is no objection raised upon expiry of the period of announcement, the company may, within 20 days, apply to the company registration authority for cancellation of registration of the company.

Where the registration of a company is cancelled through the simplified procedure, the shareholders making untrue undertakings regarding the debts are jointly and severally liable for the debts of the company before the cancellation of registration.

Overseas Listing

According to the, a Chinese domestic company that seeks overseas listing shall file the application with the CSRC according to the administrative filing procedure necessary for the Overseas Listing Trial Measures.

Merger and Demerger

Companies may merge through merger by absorption or through the establishment of a newly merged entity. If it merges by absorption, the company which is absorbed shall be dissolved. If it merges by forming a new corporation, both companies will be dissolved.

SECURITIES LAW AND REGULATIONS

The PRC has promulgated a number of regulations that relate to the issue and trading of shares and disclosure of information. In October 1992, the State Council established the Securities Committee and the CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities related institutions in the PRC and administering the CSRC. The CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions of securities markets, supervising securities companies, regulating public offers of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the two departments and reformed the CSRC.

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The Interim Provisional Regulations on the Administration of Share Issuance and Trading (《股票發行與交易管理暫行條例》) deals with the application and approval procedures for public offerings of equity securities, trading in equity securities, the acquisition of listed companies, deposit, clearing and transfer of listed equity securities, the disclosure of information with respect to a listed company, investigation, penalties and dispute settlement.

On December 25, 1995, the State Council promulgated and implemented the Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內外上市外資股的規定》). These regulations deal mainly with the issue, subscription, trading and declaration of dividends and other distributions of domestic listed and foreign invested shares and disclosure of information of joint stock limited companies having domestic listed and foreign invested shares.

The Securities Law of the People’s Republic of China (《中華人民共和國證券法》) (the “**Securities Law**”) took effect on July 1, 1999 and was revised on August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest revised Securities Law came into effect on March 1, 2020. This is the first national securities law in the PRC, which is divided into 14 chapters and 226 articles regulating, among other things, the issuance and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council’s securities regulatory authorities. The Securities Law comprehensively regulates activities in the PRC securities market. Article 224 of the Securities Law provides that domestic enterprises shall comply with the relevant provisions of the State Council to list its shares outside the PRC. Currently, the issuance and trading of foreign issued shares (including H shares) are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

On November 14, 2019, CSRC promulgated the Guidance for the Application for the “Full Circulation” of the Domestic Unlisted Shares of H-share Companies (《H股公司境內未上市股份申請“全流通”業務指引》), which came into effect on the same day and partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》). This guideline is to regulate the listing and circulation (hereinafter referred to as “**Full Circulation**”) of unlisted domestic shares of domestic joint-stock limited companies (hereinafter referred to as H-share Companies) listed on the Stock Exchange (including unlisted domestic shares held by domestic shareholders before overseas listing, unlisted domestic shares issued in China after overseas listing and unlisted shares held by foreign shareholders).

H-share Companies applying for “Full Circulation” shall submit the application to the CSRC for filing procedure. H-share companies may submit the application for “Full Circulation” separately or simultaneously when applying for overseas refinancing. Unlisted domestic joint stock limited companies may submit the application for “Full Circulation” simultaneously when applying for overseas initial public offering and listing.

APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND THE PRC COMPANY LAW

The Hong Kong law applicable to a company incorporated in Hong Kong is based on the Companies Ordinance and is supplemented by common law and the rules of equity that apply to Hong Kong. As a joint stock limited company established in the PRC that is seeking an initial listing of shares on the Stock Exchange, we are subject to the Company Law and all other rules and regulations promulgated pursuant to the Company Law.

Set out below is a summary of certain material differences between Hong Kong company law applicable to a company incorporated in Hong Kong and the Company Law applicable to a joint stock limited company incorporated and existing in accordance with the Company Law. This summary is, however, not intended to be an exhaustive comparison.

Corporate Existence

Under the Hong Kong company law, a company with share capital must be incorporated by the Registrar of Companies in Hong Kong, which will grant a registration certificate to the company upon its incorporation, and the company will acquire an independent corporate existence. A company may be incorporated as a public company or a private company.

According to the Company Law, a joint stock limited company may be incorporated by promotion or public subscription. The minimum registered capital of a joint stock limited company is not required, unless otherwise provided by laws, administrative regulations and the decisions of the State Council, for the paid-up registered capital and the minimum registered capital of a joint stock limited company.

Hong Kong law does not prescribe any minimum registered capital requirements for a Hong Kong company.

Share Capital

The Company Law does not provide for authorized share capital. The share capital of a company incorporated in Hong Kong would be its issued share capital. The full proceeds of a share issue will be credited to share capital and becomes the company's share capital. The directors of a company incorporated in Hong Kong may, with the prior approval of the shareholders if required, issue new shares of the company.

Under the Securities Law, an application for listing shall comply with the listing rules of the stock exchange. Hong Kong law does not prescribe any minimum capital requirements for companies incorporated in Hong Kong.

APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

According to the Company Law, shareholders may provide capital contribution in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws and administrative regulations). For non-monetary assets to be used as capital contributions, appraisals and assets verification must be carried out to ensure no overvaluation or under-valuation of the assets. There is no such restriction on a Hong Kong company under Hong Kong law.

Restrictions on Shareholding and Transfer of Shares

Under the PRC law, the Domestic Shares, which are denominated and subscribed for in Renminbi, can only be subscribed for and traded by PRC investors, designated qualified overseas institutional investors or qualified overseas strategic investors. Overseas listed shares, which are denominated in Renminbi and subscribed for in a foreign currency, may only be subscribed for, and traded by, investors from countries and regions outside the PRC or other qualified PRC institutional investors. If the H Shares are eligible securities under the Southbound Trading Link, they are also available for subscription and trading by domestic investors in the PRC pursuant to the rules and restrictions of Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect.

According to the Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in a joint stock limited company held by its directors, supervisors and senior management transferred each year during their term of office shall not exceed 25% of the total shares they held in the company, and the shares they held in the company cannot be transferred within one year from the listing date of the shares, and also cannot be transferred within half a year after the said personnel has left office. There are no such restrictions on shareholdings and transfers of shares under Hong Kong law apart from the six-month lockup on the company’s issue of shares and the 12-month lockup on controlling shareholders’ disposal of shares, as illustrated by the undertakings given by the Company and our Controlling Shareholders to the Stock Exchange.

Notice of General Meeting

According to the Company Law, notice of annual general meeting must be given not less than 20 days before the meeting, while notice of an extraordinary general meeting must be given not less than 15 days before the meeting. If a company has bearer shares, a public announcement of a general meeting must be made at least 30 days prior to the meeting.

For a limited company incorporated in Hong Kong, the notice period for an annual general meeting is at least 21 days and in any other case, at least 14 days for a limited company and at least 7 days for an unlimited company.

Quorum for General Meetings

The Company Law does not specify any quorum requirement for a general meeting.

APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Under Hong Kong law, the quorum for a general meeting is two members unless the articles of association of the company otherwise provide. For a single member company, one member is a quorum.

Voting at General Meetings

According to the Company Law, the passing of any resolution requires more than half of the votes held by the shareholders present in person or by proxy. Amendments to the articles of association, change of corporate form, increase or decrease of registered capital and merger, division or dissolution must be approved by shareholders or proxies representing more than two-thirds of the voting rights being present in shareholders’ general meeting.

Under Hong Kong law, (1) an ordinary resolution is passed by a simple majority of votes cast by members present in person or by proxy at a shareholders’ general meeting and (2) a special resolution is passed by a majority of not less than three-fourths of votes cast by members present in person or by proxy at a shareholders’ general meeting.

Variation of Class Rights

The Company Law has no special provision relating to variation of class rights. However, the Company Law states that the State Council can promulgate regulations relating to other kinds of shares.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (1) with the approval of a special resolution of the holders of the relevant class at a separate meeting; (2) with the consent in writing of the holders of at least three-fourths of the total voting rights of holders of shares in the class in question; (3) by agreement of all the members of a Hong Kong company or (4) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

Directors, Senior Management and Supervisors

The Company Law, unlike the Companies Ordinance, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on directors’ authority in making major dispositions, restrictions on companies providing certain benefits to directors and guarantees in respect of directors’ liability and prohibitions against compensation for loss of office without shareholders’ approval.

Supervisory Committee

According to the Company Law, a joint stock limited company’s directors and senior management are subject to the supervision of a supervisory committee. There is no mandatory requirement for the establishment of a supervisory committee for a company incorporated in Hong Kong.

APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Derivative Action by Minority Shareholders

Hong Kong law permits minority shareholders to initiate a derivative action on behalf of all shareholders against directors who have committed a breach of their fiduciary duties to the company if the directors control a majority of votes at a general meeting, thereby effectively preventing a company from suing the directors in breach of their duties in its own name.

According to the Company Law, if the directors and senior management of a joint stock limited company violate laws, administrative regulations or its articles of association, resulting in losses to the company, shareholders individually or jointly holding over 1% of the shares in the company for more than 180 consecutive days may request in writing the supervisory committee to initiate proceedings in the people's court. If the supervisors violate the relevant provisions of the Company Law, the above shareholders may request in writing the board of directors to initiate litigation at the people's court. Upon receipt of such written request from the shareholders, if the supervisory committee or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days upon receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company's interests, have the right to initiate proceedings directly to the people's court in their own name.

Protection of Minorities

Under Hong Kong law, a shareholder who complains that the affairs of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to court to either wind up the company or make an appropriate order regulating the affairs of the company. In addition, on the application of a specified number of members, the Financial Secretary of Hong Kong may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated in Hong Kong.

The Company Law provides that any shareholders holding 10% or more of the voting rights of all issued shares of a company may request a People's Court to dissolve the company to the extent that the operation or management of the company experiences any serious difficulties and the company continues to suffer serious losses and no other alternatives can resolve.

Financial Disclosure

According to the Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its shareholders' general meeting. In addition, a joint stock limited company of which the public offering Shares are offered must publish its financial report. The Hong Kong law requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial report, auditors' report and directors' report, which are to be presented before the company in its annual general meeting, not less than 21 days before such meeting.

APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

According to the Company Law, a company shall at the end of each accounting year prepare a financial report which shall be audited by the accounting firm in accordance with the laws.

Information on Directors and Shareholders

The Company Law gives shareholders the right to inspect the articles of association, minutes of the shareholders’ general meetings and financial and accounting reports. Under the articles of association, shareholders have the right to inspect and copy (at reasonable fee) certain information on shareholders and on directors similar to that available to shareholders of Hong Kong companies under the Hong Kong law.

Receiving Agents

According to the Company Law and Hong Kong law, dividends once declared are debts payable to shareholders. Under Hong Kong law, the limitation period for an action to demand repayment of a debt is six years, whereas the Civil Code of the PRC (《中華人民共和國民法典》) provides that the limitation period for an action to be taken is three years.

Corporate Reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its members pursuant to Section 673 and Section 674 of the Companies Ordinance, which requires the sanction of the court.

According to the Company Law, the merger, demerger, dissolution or change to the forms of a joint stock limited company has to be approved by shareholders at general meeting.

Statutory Deductions

According to the Company Law, a company shall draw 10% of the profits as its statutory reserve fund before it distributes any profits after taxation. When the aggregate amount of the company’s statutory reserve fund reaches 50% of the company’s registered capital, the company may no longer make allocations from the statutory reserve fund. After a company has made an allocation to its statutory reserve fund from its after-tax profit, it may make an allocation to its discretionary reserve fund from its after-tax profit upon a resolution approved at the shareholders’ general meeting. There are no such requirements under Hong Kong law.

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Remedies of Company

According to the Company Law, if a director, supervisor or senior management in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or senior management should be responsible to the company for such damages.

The Listing Rules require listed companies' articles of association to provide for remedies of the company similar to those available under Hong Kong law (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

Dividend

The company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder.

Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. The company shall not exercise its powers to forfeit any unclaimed dividend after the expiry of the applicable limitation period.

Fiduciary Duties

In Hong Kong, there is the common law concept of the fiduciary duty of directors.

Under the Company Law, directors, supervisors, managers and other senior management personnel of a company have the duty of loyalty and diligence to the company. Such persons shall abide by the articles of association of the company, perform their duties faithfully, safeguard the interests of the company, and shall not use their position and authority in the company for their personal gain.

Closure of Register of Members

The Companies Ordinance requires that the register of shareholders of a company must not generally be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days in certain circumstances) in a year, whereas, as required by the Company Law, share transfers shall not be registered within 20 days before the date of a general meeting or within five days before the base date set for the purpose of distribution of dividends.

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1. DIRECTORS AND BOARD OF DIRECTORS

(1) Power to allocate and issue shares

The Articles of Association provide that the shareholders may authorize the board of directors through a general mandate at a general meeting to allocate or issue shares of no more than 20% of all outstanding H shares. The board of directors shall prepare suggestions for share allotment or issue, which are subject to approval by the shareholders at the general meeting in the form of a special resolution. Any such allotment or issue shall be in accordance with the procedures stipulated in appropriate laws, administrative regulations and supervision rules of shares listed region.

(2) Power to dispose assets of our Company or any subsidiary

The sale of substantial assets that exceeds 30% of total assets of the latest audited financial statement are subject to approval by the shareholders at the general meeting in the form of a special resolution. The boards of directors may decide on the disposal of assets of the Company as authorized by the shareholders in a general meeting.

(3) Emoluments or compensation for directors and supervisors

The emoluments or compensation for directors and supervisors that are not representative of employees of the Company are subject to approval by the shareholders at the general meeting in the form of an ordinary resolution.

(4) Appointment, Resignation and Dismissal

The board of directors consists of nine directors, including three executive directors, three non-executive directors, three independent non-executive directors. The board of directors has one chairman. Directors are elected at the general meeting.

The chairman of the Board shall be elected and dismissed by a vote of more than one half of the directors. Provided that it is in compliance with relevant laws, regulations and rules as well as the regulatory rules of which the Company's shares are listed, the general meeting may remove any director whose term has not expired by an ordinary resolution without affecting any claim for damages that may be made pursuant to any contract.

The chairman of the Board and other directors all serve three-year terms. Upon expiration of the term, the director may be re-elected. Director can be the general manager or other senior management personnel at the same time. There is no provision in the Articles of Association that imposes any age limit for directors beyond which retirement of a director is mandatory.

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The term of office of a director shall be calculated from the date of assumption of office until the expiration of the current term of office of the board of directors. If a director is not re-elected in time for the expiration of his/her term of office, or if a director resigns during his/her term of office, resulting in the number of the board of directors being less than the minimum number required by law, before the re-elected director assumes his/her office, the original director shall still perform the duties of a director in accordance with the provisions stipulated by laws, administrative regulations, departmental rules, and the Articles of Association.

If a director resigns, the director shall notify the Company in writing, and the resignation shall take effect on the date the Company receives the notification; however, if the circumstances set forth in the preceding paragraph exist, the director shall continue to perform the duties.

None of the following persons shall serve as our director, supervisor or senior management:

- i. A person who has no civil capacity or has limited civil capacity;
- ii. A person who has been imposed penalty for the offense of corruption, bribery, embezzlement, larceny, disrupting the socialist economic order or has been deprived of political rights because of this conviction and is within five years of the expiry date of the sentence; in the case of a probation, less than two years have elapsed since the date of expiration of the probationary period;
- iii. A person who is a former director, factory manager or general manager of a company or enterprise that is bankrupt and liquidated because of poor operation, was personally liable for the bankruptcy of such company or enterprise, and is within three years of the date of completion of bankruptcy and liquidation of such company or enterprise;
- iv. A person who has served as the legal representative of a company or enterprise whose business license was revoked or was ordered to close due to violation of laws, was personally liable, and is within three years of the date on which the business license of such company or enterprise was revoked;
- v. a person listed by the people's court as dishonest judgment debtors, who has a relatively large sum of debt, which was not paid at maturity;
- vi. a person who is prohibited by China Securities Regulation Commission's from entering into the securities market and is still in such prohibition period; or
- vii. Any other person who is otherwise not eligible under laws, administrative regulations, regulations of the authorities, regulatory documents and other conditions set out by the relevant regulatory bodies.

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The election, appointment or employment of the directors, supervisors or other senior management shall be invalid if such election, appointment or employment is against the Articles of Association. If the directors, supervisors or senior management falls into the situations provided in the above-mentioned situations during their term of office, they would be dismissed by our Company.

(9) Borrowing powers

The Articles of Association do not contain any specific provisions regarding directors' exercise of lending powers.

The board of directors shall be entitled to develop proposals for our Company to issue bonds and to list its Shares, and that such bond issues must be approved by the shareholders by a special resolution at the general meeting.

(5) Duties

Directors shall comply with laws, administrative regulations, and the Articles of Association, with the following duties of loyalty to the Company:

- i. Directors shall not abuse their authority by receiving any bribe or other illegal income, and shall not embezzle any of the property of the Company;
- ii. Directors shall not misappropriate the Company's funds;
- iii. Directors shall not deposit company assets into accounts held in their own names or in the name of any other individual;
- iv. Directors shall not, in violation of the Articles of Association, lend Company funds to other people or provide guarantee for other people with Company assets without the consent of the shareholders' general meeting or the board of directors;
- v. Directors shall not enter into contracts or trade with the Company either in violation of the Articles of Association or without the consent of the shareholders' general meeting;
- vi. Unless otherwise stipulated in the Articles of Association, any director shall not take advantage of his/her position to seek business opportunities that should belong to the Company for himself/herself or for any other person, or operate business of the same kind for himself/herself or for any other person;
- vii. Directors shall not accept commissions for transactions with the Company as their own;
- viii. Directors shall not disclose Company secrets without authorization;

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- v. Directors shall provide accurate information and materials to the board of supervisors, and shall not interfere with the performance of duties by the board of supervisors or individual supervisors;
- vi. Directors shall perform their duties with reasonable care normally expected of a manager in the best interests of the Company; and
- vii. Directors shall have other diligence duties prescribed by laws, administrative regulations, departmental rules and the Articles of Association.

2. MODIFICATION OF THE ARTICLE OF ASSOCIATION

Our Company may amend the Articles of Association based on the provisions of the laws, administrative regulations and Articles of Association.

In the event that the amendments to the Articles of Association passed by the general meetings need the examination and approval of the competent authorities, these amendments shall be submitted hereto for approval. Where the amendment of the Articles of Association involves registration, it shall be necessary to carry out the lawfully prescribed procedures for registration change.

3. VARIATION OF RIGHTS OF EXISTING SHARES OF CLASSIFIED SHARES

Any plan of our Company of changing or abolishing the rights of a classified shareholder is subject to the approval of the general meeting in the form of a special resolution and the approval of the affected classified shareholders at a separately convened the general meeting before it can be implemented.

Changes or abolishment of the rights of a classified shareholder due to amendment in domestic and foreign laws, administrative regulations, listing rules, and decisions made by domestic and foreign regulatory agencies in accordance with the law do not require the approval of the general meeting or classified general meeting.

Domestic shareholders of the company transferring all or part of their shares to overseas investors and listing and trading overseas, or converting all or part of the domestic shares into overseas listed shares and listing and trading on overseas stock exchanges shall not be considered that the company intends to change or abolish the rights of classified shareholders.

The rights of a classified shareholder shall be deemed as changed or abolished under the following circumstances:

- i. Increase or decrease the number of the classified shares, or increase or decrease the number of classified shares with equal or more voting rights, distribution rights, other privileges than this type of classified shares;

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- ii. Convert all or part of the classified shares into other classes or convert another class of shares, partly or wholly, into the shares of such class;
- iii. Remove or reduce the right of the classified shares to accrued dividends generated or rights to cumulative dividends;
- iv. Reduce or remove a dividend preference or a liquidation preference attached to shares of such class;
- v. Add, remove or reduce the right of the classified shares to convert share rights, options rights, voting rights, transfer rights, and pre-emptive rights, or the right to obtain the securities of our Company;
- vi. Remove or reduce the right of the classified shares to receive funds payable of our Company in specified currencies;
- vii. Create new classified shares entitled to equal or more voting rights, distribution rights, or other privileges than the classified shares;
- viii. Restrict the transfer or ownership of the classified shares or increase such restrictions;
- ix. Issue subscription or conversion rights for this or other classified shares;
- x. Increase the rights and privileges of other classes of shares;
- xi. The restructuring plan of our Company may constitute different classes of shareholders to assume responsibilities disproportionately in restructuring; and
- xii. Amend or abolish clauses stipulated in our Articles of Association.

Whether or not the affected classified shareholders have voting rights at the general meeting, in the event of matters described above from ii through viii, xi to xii, they have voting rights at the classified general meeting, but the shareholders that have interests at stake shall have no voting rights at the classified general meeting. Shareholders that have interests at stake include:

- i. Where the Company makes an offer to all the shareholders at the same ratio according to this Articles of Association or purchase their own shares through public transaction in the stock exchange, shareholders that have interests at stake refer to controlling shareholders as defined in this Articles of Association;
- ii. Where our Company purchase its own shares through reaching an agreement outside the Stock Exchange and in accordance with the Articles of Association, shareholders that have interests at stake shall mean the shareholders who are relevant to such agreement;

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- iii. In our Company's re-organization plan, shareholders that have interests at stake shall mean shareholder who bear liability at a rate that is lower than other shareholders in the same class or who hold different interests with other shareholders in the same class.

The resolution of the classified general meeting shall be passed by votes representing more than two thirds of shareholding with voting rights attending the classified general meeting.

If the number of shares with voting rights represented by shareholders intending to attend the meeting is more than half of the total number of that category of shares with voting rights, the company may convene the classified general meeting; if not, the company shall, within five days, notify the shareholders once again through a public announcement of the matters to be deliberated at the meeting, as well as the date and venue of the meeting. After the announcement is published, the company may convene a classified general meeting.

Insofar as possible, any classified general meeting shall be held in accordance with the same procedures as those of the general meeting, and unless otherwise provided in the Articles of Association, any clause that relates to the procedures for convening the general meeting in the Articles of Association shall apply to classified general meeting.

Apart from the holders of other classified shares, the holders of Domestic Shares, the holders of overseas listed foreign shares, and the holders of overseas unlisted shares are deemed as different classified shareholders.

4. SPECIAL RESOLUTIONS NEEDED TO BE ADOPTED BY ABSOLUTE MAJORITY VOTE

The resolutions of the general meeting shall be divided into ordinary resolutions and special resolutions.

An ordinary resolution may be adopted by a simple majority of the votes held by the shareholders (including proxies of shareholders) attending the general meeting.

A special resolution can be adopted by a two-thirds majority of the votes held by the shareholders (including proxies of shareholders) attending the general meeting.

5. VOTING RIGHTS

The ordinary shareholders have the right to attend or appoint a proxy to attend and vote at the general meeting. When voting at the general meeting, the shareholder (including proxy) may exercise his or her voting rights in accordance with the number of shares with voting power held with each share representing one vote.

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Any shareholder who is required by the Listing Rules to abstain from voting on a matter or is limited to an affirmative or negative vote shall abstain from voting or be required to so vote; any vote cast by or on behalf of relevant shareholder which is cast in violation of such requirement or restriction shall not be counted in the voting result.

The shares held by the Company itself shall have no voting right and shall not be counted in the total number of voting shares at the general meeting.

6. RULES ON GENERAL SHAREHOLDERS' MEETINGS

The general meetings are divided into annual general meetings and extraordinary general meetings. The annual general meeting shall be convened once a year and be held within six months of the end of the previous fiscal year.

7. ACCOUNTING AND AUDITS

(1) Financial and accounting policies

Our Company shall develop its financial accounting policies pursuant to laws, administrative regulations and rules developed by the competent department.

The interim results or financial information published or disclosed by our Company shall at the same time be prepared in accordance with the PRC accounting standards, rules and regulations as well as international accounting standards or the accounting standards of the overseas area in which the shares are listed.

Our Company shall publish the financial reports twice in each accounting year. Interim financial reports shall be published within 60 days of the end of the first six months of a fiscal year, while the annual financial report shall be published within 120 days of the end of each accounting year.

(2) Appointment and Dismissal of Accountants

Our Company shall appoint a reputable accounting firm that meets appropriate requirements of the relevant regulations of the PRC to be responsible for auditing its annual financial report and reviewing its other financial reports.

The term of the accounting firm shall be one year.

If the position of an appointed accounting firm is vacant, the board of directors may appoint an accounting firm before the start of general meeting. However, if during the vacant period, our Company has other incumbent accounting firm, such accounting firm may take the vacant.

Except the circumstances as above said, our Company shall appoint an accounting firm by the decision of the general meeting. The shareholders may replace the accounting firm through an ordinary resolution at the general meeting.

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8. NOTICE AND AGENDA OF GENERAL SHAREHOLDERS' MEETINGS

The general meeting is the authorized organ of our Company that performs duties and exercises powers in accordance with the law.

Under any of the following circumstances, the board of directors shall convene an extraordinary general meeting within two months:

- i. The number of directors is less than the number specified in the PRC Company Law or less than two thirds of the number required in the Articles of Association;
- ii. The uncovered losses of our Company reach one-third of its total paid-in registered capital;
- iii. The shareholders with 10% or more shares of the Company separately or jointly request to convene an extraordinary general meeting in writing (the number of shares shall be calculated by the day of the request);
- iv. The board of directors considers it necessary;
- v. Two or more independent non-executive directors make such proposal;
- vi. The board of supervisors makes such proposal;
- vii. Any other circumstances stipulated in laws, regulations, the Listing Rules, the Articles of Association.

In the event that the general meeting is convened, the board of directors, the board of supervisors and shareholders who separately or jointly hold more than 1% of the shares of our Company may submit a proposal with time limit set by the Listing Rules.

When convening a general meeting, our Company shall send a written notice 21 days before it is convened. When convening an extraordinary general meeting, our Company shall send a written notice 15 days before it is convened.

The extraordinary general meeting shall not decide on issues which are not listed in the notice.

The notice of the general meeting shall be made in writing, including the following contents:

- i. The place, the date and the hour of the meeting;
- ii. The matters and proposals to be discussed at the meeting;

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- iii. Conspicuous statement that all shareholders are entitled to attend the meeting and appoint proxy to attend and vote and that proxy need not be a shareholder;
- iv. The date of record for the shareholders who are entitled to attend the meeting;
- v. The name and telephone number of the contact person for the meeting;
- vi. The time and procedure of voting online or by any other means;
- vii. other requirements stipulated by laws, administrative regulations, department rules, Listing Rules or these Articles of Association.

The resolution of the general meeting includes ordinary resolution and special resolution. The following matters shall be approved by the general meeting through ordinary resolutions:

- i. Work report of the board of directors and the board of supervisors;
- ii. Plans of earnings distribution and loss make-up schemes drafted by the board of directors;
- iii. Appointment or dismissal of the members of the board of directors and the board of supervisors, and their enumeration and payment methods;
- iv. Annual budget and closing account report, balance sheet, income statement and other financial statements;
- v. Annual reports of the Company;
- vi. Other matters other than those approved by special resolution stipulated in the laws, administrative regulations, Listing Rules or the Articles of Association.

The following matters shall be approved by special resolution at the general meeting:

- i. The increase or decrease of the registered capital;
- ii. Division, merger, dissolution and liquidation of our Company;
- iii. Amendment of the Articles of Association;
- iv. The purchase or sale by the Company within one year of material assets exceeding 30% of the audited total assets of the Company at latest audited financial statement;
- v. Share incentive scheme;
- vi. Other matters recognized by ordinary resolution of the general meeting that could materially affect our Company and need to be approved by special resolution or as required by the laws, administrative regulations, Listing Rules or the Articles of Association.

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SUMMARY OF ARTICLES OF ASSOCIATION

In the event that any resolution of the general meeting or resolution of the board of directors violates laws or administrative regulations, any shareholder is entitled to request the court to deem it as invalid.

In the event that the convening procedure or voting formula of the shareholders meeting or meeting of the board of directors violates any of laws, administrative regulations or the Articles of Association, or resolution of which violates the Articles of Association, any shareholder is entitled to ask the court to overturn within 60 days after the resolution was adopted, unless there is only a minor defect in the procedures for convening a general meeting or a meeting of the board of directors or in the manner of voting, which does not materially affect the resolution.

Shareholders who have not been notified to attend the general meeting may, within 60 days from the date when they know or should have known that the resolution of the general meeting has been made, request the people's court to revoke it; if they do not exercise the right of revocation within one year from the date when the resolution has been made, the right of revocation is extinguished.

9. SHARES TRANSFERS

The shares issued before the public issuance of shares by our Company shall not be transferred within one year of the date on which the stocks of our Company are listed and traded on a securities exchange.

The directors, supervisors, and senior management of our Company shall declare, to our Company, information on their holdings of the shares of our Company and the changes thereto. The shares transferrable by them during each year of their term of office shall not exceed 25 percent of their total holdings of the shares of our Company. The shares that they held in our Company shall not be transferred within one year of the date on which the stocks of our Company are listed and traded. The aforesaid persons shall not transfer their shares of our Company within six months from the date of their resignation.

With regard to the H Shares that capital of which has been full-paid could be transferred without limitation in accordance with the Articles of Association. However, unless meeting the following conditions, the board of directors may refuse to recognize any transfer document without giving any reason:

- i. Document that related to any share ownership or transfer documents that may affect the ownership of the shares shall be registered and such payment shall not exceed the maximum fee provided by the listing rules of the stock exchange from time to time;
- ii. The transfer documents only involve H Shares listed in Hong Kong;
- iii. The stamp duty chargeable on the transfer documents has been paid;

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- iv. The relevant share certificate, and upon the reasonable request of the board of directors, any evidence in relation to the right of the transferor to transfer the shares has been submitted;
- v. If the shares are to be transferred to joint holders, the number of the joint holders shall not exceed four;
- vi. Our Company does not have any lien on the relevant shares; and
- vii. The shares shall not be transferred to minors or the person who is insane or is found to be of unsound mind.

10. RIGHTS OF OUR COMPANY TO PURCHASE OUR OUTSTANDING ISSUED SHARES

Under any of the following circumstances, our Company may submit to relevant competent authorities for approval to buy back our outstanding issued shares according to legal procedures with the approval of procedures stipulated in the Articles of Association:

- i. Reduce our Company's registered capital;
- ii. Merger with other companies which hold our shares;
- iii. Granting shares to the staff of our Company as incentives;
- iv. Requesting the Company to buy back its shares from shareholders who vote against any resolutions adopted at the general meeting concerning the merger and division of the Company;
- v. To convert shares into bond issued by our Company which is convertible to stock of our Company;
- vi. Necessary for our Company to maintain our Company's value and shareholders' equity; or
- vii. Other circumstances as permitted by the laws, administrative regulations, regulations of the authorities and Listing Rules.

11. POWER FOR ANY SUBSIDIARY OF OUR COMPANY TO OWN SHARES IN ITS PARENT

There are no provisions in the Articles of Association relating to ownership by subsidiary of our Company of shares in its parent.

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SUMMARY OF ARTICLES OF ASSOCIATION

12. DIVIDEND AND OTHER DISTRIBUTION METHODS

The Company may distribute dividends in the following manner of cash or stock. A shareholder is entitled to receive interest with regard to payment of the shares which was paid before reminder notice. However, advance payment of the shares is not subject to any further dividend thereof.

Our Company shall appoint receiving agents on behalf of shareholders holding overseas listed foreign shares.

Receiving agents shall receive dividends and other payable funds that are distributed with respect to our overseas listed foreign shares for relevant shareholders. Receiving agents appointed by our Company shall on behalf of shareholders of shares listed in Hong Kong Stock Exchange shall be a trust company registered under the Trustee Ordinance of Hong Kong.

13. SHAREHOLDER PROXIES

Shareholders may attend the shareholders' general meeting in person or authorize proxies to attend and vote on their behalf. A legal person shareholder should attend the meeting by its legal representatives or persons authorized by its board of directors or other decision-making authorities.

Any blank power of attorney form sent by the directors to the shareholder for appointing a shareholder proxy shall allow the shareholder, according to his or her free will, to instruct the proxy to vote and provide instructions separately for matters to be put to vote on each item on the meeting agenda.

14. REVIEW THE REGISTER OF SHAREHOLDERS AND OTHER RIGHTS OF SHAREHOLDERS

Our Company shall make a register of shareholders in accordance with evidentiary documents provided by the securities registration authorities.

Pursuant to the understanding and agreement entered into between the competent agency in charge of securities of the PRC and the overseas securities regulatory authorities, our Company may keep the original register of the shareholders of the overseas listed foreign shares overseas and entrust an overseas entity to manage it. The original register of the shareholders of the overseas listed foreign shares listed in Hong Kong shall be kept in Hong Kong.

Our Company shall keep a copy of the register of the holders of the overseas listed foreign shares at our residential address. The overseas entrusted agency shall at all times maintain consistency between the original and copy of the register of the holders of the overseas listed foreign shares.

In case of inconsistency between the original and copy of the register of the holders of the overseas listed foreign shares, the original shall prevail.

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When our Company convenes the general meeting, pays dividends, goes into liquidation or is involved in other actions that require the confirmation of identities, the board of directors shall fix a date as the equity registration date, upon expiration of which the shareholders whose names registered on the register of shareholders shall be the shareholders entitled to relevant equity.

15. RESTRICTIONS ON RIGHTS OF CONTROLLING SHAREHOLDER

The controlling shareholder, de facto controller, directors, supervisors and senior management of the Company shall not take advantage of their associated relationship to damage the Company's interests. Any loss caused to the Company as a result of such violation shall be compensated.

The controlling shareholder and de facto controller of the Company are obliged to act in good faith to the Company and the general public company shareholders. The controlling shareholder shall exercise their rights as capital contributors in strict accordance with the law and shall not impair the lawful rights and interests of the Company or of the general public company shareholders by means of the distribution of profits, reorganization of assets, external investment, misappropriation of assets, loan, or guaranty, nor shall he make use of his controlling position to impair the interests of the Company or of the general public company shareholders.

16. PROCEDURES FOR LIQUIDATION

Under any of the following circumstances, our Company shall be lawfully dissolved and liquidated:

- i. The term of business of our Company has expired or other events of dissolution occur under the Article of Association;
- ii. The general meeting adopts a resolution to dissolve our Company;
- iii. Our Company needs to be dissolved for the purpose of merger or division;
- iv. The business license is revoked, or our Company is ordered to close or be eliminated according to applicable law; or
- v. Where our Company encounters significant difficulties in business and management, continuous survival may be significantly detrimental to the interests of the shareholders, and the difficulties may not be overcome through other means, shareholders who hold more than 10% of all voting rights of the Company's shareholders may request the people's court to dissolve the Company.

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Where our Company is dissolved due to the provisions set forth in i, ii, iv and v above, the directors shall be the obligators of liquidation. A liquidation team shall be established within 15 days from the date of the event leading to liquidation to commence dissolution and the personnel of the liquidation team shall consist of the persons determined by the directors or the general meeting. In the event the liquidation team is not established to conduct liquidation during such period, the creditors can request the people's court to appoint relevant personnel to establish the liquidation team for liquidation.

The liquidation group shall consist of directors, unless the articles of association provide otherwise or the general meeting resolves to elect another person. If the liquidation obligor fails to fulfill its liquidation obligations in a timely manner and causes losses to the company or creditors, it shall be liable for compensation.

Within 10 days of the establishment of the liquidation team, the creditors shall be notified and an announcement shall be published within 60 days. The creditors shall declare their claims to the liquidation team within 30 days of the date on which the notice is received or 45 days of the date of announcement if the notice is not received.

Creditors who declare claims shall state relevant issues related to the claims and provide proofs. The liquidation team shall carry out registration of the claims.

During the period for declaration of claims, the liquidation group shall not make any repayment to the creditors.

During the liquidation, our Company shall continue to exist, but shall not carry out business activities irrelevant to the liquidation. The property of our Company shall not be distributed to any shareholder before full payments have been made out of the property according to the aforesaid provision.

In the event the liquidation team finds that, after taking stock of our Company's property and preparing the balance sheet and list of property, that the assets are insufficient to pay the debts, it shall apply to the people's court for bankruptcy liquidation. Following the acceptance of the bankruptcy application by the people's court, the liquidation group shall hand over all matters relating to the liquidation to the bankruptcy administrator designated by the people's court.

The members of the liquidation group shall be obliged to perform their liquidation duties with loyalty and diligence.

If a member of the liquidation group is negligent in performing his liquidation duties and causes losses to the company, he shall be liable for compensation.

After our Company is declared bankrupt by ruling of the people's court, the liquidation team shall turn over matters regarding the liquidation to the people's court.

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Upon closure of liquidation of our Company, the liquidation team shall prepare a liquidation report, and shall be submitted to our general meeting or the people's court for recognition. The liquidation team shall submit the above-mentioned documents to our Company registration authority and apply for cancellation of our registration and publish an announcement on our termination.

17. OTHER IMPORTANT PROVISIONS FOR OUR COMPANY OR SHAREHOLDERS

(1) General Provisions

Our Company is a permanently existing joint stock limited company.

According to the Articles of Association, any shareholder may bring a lawsuit against another shareholder, a director, a supervisor, or the senior management, any shareholder may bring a lawsuit against the Company, and the Company may bring a lawsuit against any shareholder, director, supervisor or the senior management.

(2) Share and Transfer

Our Company may increase stock capital by the following means:

- i. Issuing shares in a public offering;
- ii. Issuing shares via a private placement;
- iii. Giving bonus shares to existing shareholders;
- iv. Converting reserve funds into shares; and
- v. Other means approved by the laws, administrative regulations and relevant regulatory authorities.

Our Company may decrease our registered capital and shall comply with the procedures stipulated in Company Law of the PRC, other related regulations and the Articles of Association.

(3) Shareholders

Shareholder is entitled to rights and assumes obligations pursuant to the classification of his or her shares. Shareholder holding the same classified share has the same rights and assumes the same obligations.

APPENDIX VI **SUMMARY OF ARTICLES OF ASSOCIATION**

The rights of our ordinary shareholders are as follows:

- i. To receive distribution of dividends and other forms of benefits according to the number of shares held;
- ii. To participate in or appoint a shareholder proxy to participate in and exercise corresponding voting rights at the general meeting;
- iii. To supervise and manage business and operational activities of our Company, provide suggestions or submit queries;
- iv. To transfer, grant and pledge the Company's shares held according to the provisions of the laws, administrative regulations and the Articles of Association;
- v. To obtain relevant information according to the provisions of the Articles of Association, including:
 - (i) Obtaining the Articles of Association after the cost is paid;
 - (ii) Right to inspect and copy information as follows after the reasonable fee is paid:
 - (1) All parts of the register of shareholders;
 - (2) Personal information of the director, supervisor, or senior management, including:
 - (a) Current and former name and alias;
 - (b) Principle address (domicile);
 - (c) Nationality;
 - (d) Full-time and other part-time occupation/position;
 - (e) Identity documents and ID number;
 - (3) Share capital status of our Company;
 - (4) A report of the total book value, the number, the highest buying price and the lowest buying price for each class of shares repurchased by our Company since the last financial year, and of all expenses incurred thereon;
 - (5) Meeting minutes of the general meeting;

APPENDIX VI

SUMMARY OF ARTICLES OF ASSOCIATION

- (6) Latest audited financial statement of the Company and the reports of the board of directors, the board of supervisors, and auditors;
- (7) Copy of annual report as filed with market regulation administration and other authorities;
- (8) Receipt of corporate bond, decisions of meeting of board of directors and decisions of meeting of board of supervisors; and
- (9) Minutes of shareholder's general meeting.

A shareholder requesting inspection of the accounting books and accounting vouchers of the Company shall submit a written request, stating the purpose of consultation. If the Company has a reasonable basis to believe that the shareholder requests inspection of the accounting books and accounting vouchers for any improper purpose that may harm the lawful interests of the Company, the Company may decline provision of consultation, but shall provide a written reply to the shareholder with an explanation of the reason within 15 days of submission of the written request by the shareholder. If the Company declines provision of inspection, the shareholder may bring a lawsuit against the Company in a people's court.

A shareholder may authorize an accounting firm, a law firm, and other intermediaries to consult the materials set out in the preceding paragraph. The shareholder and the accounting firm, law firm, or any other intermediary authorized by the shareholder shall comply with the provisions of laws and administrative regulations on the protection of state secrets, trade secrets, individual privacy, and personal information in inspecting and copying the relevant materials.

Where a shareholder requests inspecting or copying of the relevant materials of a wholly-owned subsidiary of the company, the provisions of the preceding two paragraphs apply.

- vi. To participate in the distribution of the remaining assets of our Company according to the proportion of shares held upon our termination or liquidation;
- vii. To request the Company to buy back their shares as dissenting shareholders in decision of merger or division of the Company;
- viii. Other rights conferred by laws, administrative regulations, regulations of the authorities, regulatory rules where our Company's shares are listed, or the Articles of Association.

APPENDIX VI

SUMMARY OF ARTICLES OF ASSOCIATION

(5) The Board of Directors

The board of directors is responsible to the general meeting and exercises the following powers:

- i. To convene the general meeting and report on work to the general meeting;
- ii. Implement the resolutions of the general meeting;
- iii. Determine the business and investment plans of our Company;
- iv. Devise the annual financial budget and closing account plans of our Company;
- v. Devise the earnings distribution and loss offset plans of our Company;
- vi. Formulate the plans for increasing or decreasing our Company's registered capital, the issuance of corporate bonds;
- vii. Formulate plans for major acquisition, share buy-back, corporate merger, separation and dissolution of our Company;
- viii. Determine, within the scope authorized by the general meeting, such matters as the Company's external investments, the purchase and sale of assets, asset mortgages, external guarantees, entrusted management of finance, related-party transactions and external donations;
- ix. Decide on the setup of our Company's internal management organization;
- x. Appoint or dismiss the general manager, secretary of the board, and other senior managers of our Company; based on the nomination of the general manager, appoint or dismiss senior management of our Company such as deputy general manager, Chief financial officer (CFO) and other senior managers and determine their remuneration;
- xi. Set the basic management systems of our Company;
- xii. Make the modification plan to the Articles of Association;
- xiii. Make proposals to the shareholders' general meeting on the appointment or replacement of the accounting firm that provides auditing services to the Company;
- xiv. Hear work report of senior managers and to inspect the manager's work;
- xv. Formulate and implement share incentive plans of the Company; and
- xvi. Other powers and duties authorized by the laws, administrative regulations, regulations of the authorities, listing rules of the place where the shares of our Company are listed and the Articles of Association.

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Meetings of the board of directors shall be attended by more than one-half of the directors (including proxies) before the board of directors meeting can be convened.

All major matters requiring decision-making by the Board of Directors of the Company must be notified to all directors in advance in accordance with the time stipulated in these Articles of Association, together with sufficient information and in strict accordance with the prescribed procedures. Directors may request additional information to be provided. When more than one-fourth of the directors or more than two independent non-executive directors consider that the information and materials are insufficient or other matters render them unable to make judgment on the relevant matters, they may jointly propose to postpone the meeting of the Board of Directors or to postpone the deliberation of part of the matters discussed by the Board of Directors, and the Board of Directors shall adopt such proposal. The Board of Directors of the Company shall give an explanation to the general meeting on the non-standard audit opinion issued by the certified public accountants on the financial reports of the Company.

(6) Independent Non-executive director

The board of directors of the Company has three independent non-executive directors. At least one independent non-executive director shall have applicable professional qualification or are equipped with applicable accounting or relevant financial management expertise.

(7) Secretary of the Board of Directors

Our Company shall have one secretary of the board of directors.

(8) Board of Supervisors

Our Company shall set up a board of supervisors.

The board of supervisors consists of three supervisors and includes one chairman. The chairman of the board of supervisors shall be elected and dismissed by a majority vote of the members of the board of supervisors.

The board of supervisors shall consist of shareholder's representatives and employee's representatives. The supervisors assumed by the employee representatives shall be elected and dismissed democratically by the employees and shall account for no less than one-third of the board of supervisors of our Company.

Resolutions of the board of supervisors shall require approval from two-third of all the supervisors. The supervisors serve three-year terms.

The supervisors may, after the expiration of the term of office, be re-elected and re-appointed.

The directors and senior management shall not also serve as supervisors.

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SUMMARY OF ARTICLES OF ASSOCIATION

The board of supervisors is responsible to the general meeting and lawfully exercises the following powers:

- i. Examine the financial standing of our Company;
- ii. Supervise the Company's duties performing of directors and senior management, and put forward suggestions for dismissing any directors or senior management who are in breach of the laws, administrative regulations, the Articles of Association or resolutions of the general meetings;
- iii. Require the directors and senior management to take corrective measures when their actions are detrimental to the Company's interests;
- iv. Examine the financial reports, business reports, profit distribution plans and other financial documents to be submitted to the general meetings by the board of directors. If questions arise over such documents, certified public accountants and practicing auditors may be entrusted in our Company's name to assist in verification of doubtful documents;
- v. Propose to convene an extraordinary general meeting and to convene and preside over the shareholders' general meeting when the board of directors fails to perform its duty to convene and preside over a general meeting prescribed in the Company Law;
- vi. Submit proposals to the general meetings;
- vii. Bring a lawsuit against any director or senior manager in accordance with the Company Law;
- viii. Conduct investigation if any abnormality in the operation of the Company is found, and, where necessary, engage an accounting firm, law firm or any other specialized agency to assist in its work at the expense of the Company;
- ix. Other powers and duties stipulated in laws stipulated in laws, regulations, regulatory documents and the Articles of Association.

The supervisors may attend the meetings of the board of directors, query or provide suggestions on the resolution matters of the Board meeting.

(9) General manager

Our Company has one general manager, appointed or dismissed by the board of directors. The general manager of our Company is responsible to the board of directors and exercises the following powers:

- i. Be in charge of the producing and operational management of our Company, organize the enforcement of resolutions of the board of directors and report to the board of directors on work;

APPENDIX VI

SUMMARY OF ARTICLES OF ASSOCIATION

- ii. Organize the implementation of the annual operation plans and investment schemes decided by the board of directors;
- iii. Formulate the structure scheme of the internal management department of our Company;
- iv. Formulate the fundamental management policies of our Company;
- v. Formulate the specific management rules of our Company;
- vi. Propose the appointment or dismissal of the Company's deputy general manager (executive president), Chief financial officer and other senior management;
- vii. Appoint or dismiss other management personnel except those who shall be appointed or dismissed by the board of directors;
- viii. Other responsibilities authorized by the Articles of Association and the board of directors.

(10) Reserves

When the annual after-tax earnings of our Company are distributed, our Company must allocate 10% of the earnings to the statutory reserve of the Company.

When the total amount of the statutory reserve exceeds 50% of our Company's registered capital, no more allocations need to be drawn.

If the Company's statutory reserve is insufficient to offset our losses during the previous year, the earnings generated during the current year must be used to make up the losses before allocating the statutory reserve in accordance with the requirements set forth above.

After allocation to the statutory reserve from the after-tax earnings of our Company, we may also allocate to the reserves at will from after-tax earnings in line with the resolution(s) adopted at the general meeting.

After our Company has made up for its losses and made allocations to its statutory reserve fund, the remaining profits are distributed in proportion to the number of shares held by the shareholders, unless otherwise specified by the Articles of Association.

If the general meeting or directors violates the above provisions and profits are distributed to the shareholders before the Company makes up for losses or makes allocations to the statutory reserve fund, the profits distributed in violation of the provisions must be returned by such shareholders to the Company. If the Company suffers losses, the shareholders and responsible directors, supervisors and senior management shall be liable for compensation.

The shares held by our Company itself shall not be subject to profit distribution.

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SUMMARY OF ARTICLES OF ASSOCIATION

The Company's reserves may be used only for offsetting losses of the Company, expanding the scale of business and operations or for conversion into capital to increase our capital. Where reserves are used to cover loss of a company, the discretionary and statutory reserves shall be first used; if they are insufficient for covering loss, the capital reserve fund may be applied to make up the company's losses. Where the statutory reserve converses into capital, the remaining statutory reserve shall not be less than 25% of the registered capital of our Company before such conversion.

APPENDIX VII STATUTORY AND GENERAL INFORMATION

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

Our Company was established in the PRC on January 21, 2013 and was converted to a joint stock company with limited liability on April 28, 2023. As of the Latest Practicable Date, the registered share capital of our Company was RMB150,000,000.

Our Company has established a place of business in Hong Kong at 31/F., Tower Two, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong and was registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on January 16, 2025. Ms. Au Wing Sze (區詠詩), the joint company secretary of our Company, has been appointed as out authorized representative for the acceptance of service of process in Hong Kong whose correspondence address is the same as our place of business in Hong Kong.

As our Company was established in the PRC, its operations are subject to the relevant laws and regulations of the PRC. A summary of the relevant aspects of laws and regulations of the PRC and the Article of Association is set out in Appendices V and VI to this document, respectively.

2. Changes in the Share Capital of Our Company

On January 21, 2013, our Company was established as a limited liability company with a registered capital of RMB5 million. The following sets out changes in the share capital of our Company within the two years immediately preceding the date of this document:

On December 31, 2024, the share capital of our Company increased from RMB6,361,242 to RMB6,600,724, comprising 6,600,724 Shares with a nominal value of RMB1.00 each.

In January 2025, the share capital of our Company increased from RMB6,600,724 to RMB150,000,000, comprising 150,000,000 Shares with a nominal value of RMB1.00 each.

For details, see “History, Development and Corporate Structure” in this document. Save as disclosed above, there has been no alteration in our share capital within two years immediately preceding the date of this document.

3. Changes in the Share Capital of our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries is set out in the section headed “History, Development and Corporate Information” and note 41 to the Accountants’ Report as set out in Appendix I to this document.

APPENDIX VII STATUTORY AND GENERAL INFORMATION

The following sets out the changes in the share capital of our subsidiaries within the two years immediately preceding the date of this document:

Yingjiu Health

On December 6, 2023, Yingjiu Health was established in the PRC as a limited liability company with a registered capital of RMB1,000,000.

Qingdao Antai

On April 28, 2024, Qingdao Antai was established in the PRC as a limited liability company with a registered capital of RMB50,000,000.

4. Resolutions of Our Shareholders

Pursuant to a general meeting of our Company held on January 24, 2025, the following resolutions, among others, were passed by our Shareholders:

- (a) the [REDACTED] by our Company of H Shares of nominal value of RMB1.00 each and that such H shares be [REDACTED] on the Hong Kong Stock Exchange;
- (b) that the number of H Shares to be [REDACTED] shall not be more than [REDACTED]% of the total issued share capital of our Company as enlarged by the [REDACTED] (before the exercise of the [REDACTED]), and the grant to the [REDACTED] (or their representatives) of the [REDACTED] of not more than [REDACTED]% of the number of H Shares [REDACTED] pursuant to the [REDACTED];
- (c) subject to the completion of the [REDACTED], the adoption of the Articles of Association which shall become effective on the [REDACTED], and the authorization to the Board to amend the Articles of Association in accordance with the requirements of the relevant laws and regulations and the Listing Rules; and
- (d) authorization of our Board to handle all relevant matters relating to, among other things, the [REDACTED] and [REDACTED] of the H shares.

B. FURTHER INFORMATION ABOUT THE BUSINESS OF THE COMPANY

1. Summary of Material Contract

We have entered into the following contract (not being a contract entered into in the ordinary course of business) within the two years immediately preceding the date of this document that is or may be material:

- (a) the [REDACTED].

APPENDIX VII STATUTORY AND GENERAL INFORMATION

2. Intellectual Property Rights

Trademarks

As of the Latest Practicable Date, we have registered the following trademarks, which we consider to be material to our business:

No.	Trademark	Owner	Registration no.	Place of registration	Class	Validity period
1.		Our Company	68638023	PRC	1	May 7, 2024 - May 6, 2034
2.		Our Company	68645924	PRC	35	May 7, 2024 - May 6, 2034
3.		Our Company	21904490	PRC	42	February 7, 2018 - February 6, 2028
4.	VIGONVITA	Our Company	27180530	PRC	42	October 7, 2018 - October 6, 2028
5.	VIGONVITA	Our Company	27180531	PRC	5	October 21, 2018 - October 20, 2028
6.	VIGONVITA	Our Company	27180532	PRC	1	October 7, 2018 - October 6, 2028
7.	旺山旺水	Our Company	40937325	PRC	42	October 14, 2020 - October 13, 2030
8.	旺山旺水	Our Company	40936417	PRC	35	October 7, 2020 - October 6, 2030
9.	思美瑞非	Our Company	43649087A	PRC	35	October 28, 2020 - October 27, 2030
10.	斯美瑞非	Our Company	43671084	PRC	1	September 14, 2020 - September 13, 2030
11.	Simmerafil	Our Company	59374962	PRC	1	March 7, 2022 - March 6, 2032
12.		Our Company	59501676	PRC	5	October 7, 2022 - October 6, 2032
13.	renmindevir	Our Company	59650214	PRC	5	March 21, 2022 - March 20, 2032
14.	旺连	Our Company	59729883	PRC	5	March 28, 2022 - March 27, 2032
15.	民得维	Our Company	59966577	PRC	5	April 7, 2022 - April 6, 2032
16.	民的韦	Our Company	59959819	PRC	5	March 21, 2022 - March 20, 2032
17.	昂为	Our Company	60329043	PRC	5	April 28, 2022 - April 27, 2032

APPENDIX VII STATUTORY AND GENERAL INFORMATION

No.	Trademark	Owner	Registration no.	Place of registration	Class	Validity period
18.	民得卫	Our Company	60414064	PRC	5	May 7, 2022 - May 6, 2032
19.	昂扬有为	Our Company	60409282	PRC	5	May 7, 2022 - May 6, 2032
20.	ONVITA	Our Company	60564546	PRC	5	July 7, 2022 - July 6, 2032
21.	Mindvy	Our Company	61636719	PRC	5	June 14, 2022 - June 13, 2032
22.	vinnerna	Our Company	62399237	PRC	5	July 21, 2022 - July 20, 2032
23.	昂伟达	Our Company	73305783	PRC	5	February 14, 2024 - February 13, 2034
24.	昂伟达	Our Company	74917297	PRC	5	April 21, 2024 - April 20, 2034
25.	昂伟达	Our Company	74913240	PRC	10	April 21, 2024 - April 20, 2034
26.	昂伟达	Our Company	74922384	PRC	32	April 28, 2024 - April 27, 2034
27.	昂伟达	Our Company	75950359	PRC	35	June 28, 2024 - June 27, 2034

As of the Latest Practicable Date, we had applied for the registration of the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Applicant	Place of registration	Application number	Application date
1	旺山旺水	Our Company	Hong Kong	306743872	December 3, 2024
2	VIGONVITA	Our Company	Hong Kong	306743881	December 3, 2024
3	(A) 	Our Company	Hong Kong	306743890	December 3, 2024
	(B) 				

APPENDIX VII STATUTORY AND GENERAL INFORMATION

Patents

Please see the paragraph headed “Business — Intellectual Property” in this document for patents registered as of the Latest Practicable Date, which we considered to be material to our business.

Copyrights

As of the Latest Practicable Date, we have registered the following copyrights, which we consider to be material to our business:

<u>No.</u>	<u>Copyright</u>	<u>Author</u>	<u>Registration number</u>	<u>Date of publication</u>	<u>Registration</u>
1	英久	Our Company	國作登字 -2024-F- 00189498	May 13, 2024	July 3, 2024
2	山水logo	Our Company	國作登字 -2023-F- 00101016	February 19, 2023	May 26, 2023

Domain Names

As of the Latest Practicable Date, we have registered the following domain names, which we consider to be material to our business:

<u>No.</u>	<u>Owner</u>	<u>Domain Name</u>	<u>Registration Date</u>
1	Our Company	vigonvita.cn	January 15, 2014
2	Our Company	vigonvita.com	January 15, 2014
3	Our Company	旺山旺水.商標	December 21, 2023

Save as disclosed above, as of the Latest Practicable Date, there was no other trade or service mark, patent, intellectual or industrial property right which was material in relation to our business.

APPENDIX VII STATUTORY AND GENERAL INFORMATION

C. FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interests

Save as disclosed below, immediately following completion of the [REDACTED] (without taking into account the H Shares which may be [REDACTED] and [REDACTED] pursuant to the exercise of the [REDACTED]), so far as our Directors are aware, none of our Directors, Supervisors and chief executive has any interest or short positions in our Shares, underlying Shares or debentures of our Company or any associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to our Company and the Hong Kong Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they are taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to our Company and the Hong Kong Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules.

<u>Name</u>	<u>Position</u>	<u>Nature of Interest</u>	<u>Number and class of Shares held</u>	<u>Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED]</u> (%)	<u>Approximate percentage of shareholding in the total share capital of our Company after the [REDACTED]</u> (%)
Dr. Tian	Chairman of the Board, executive Director, chief executive officer and general manager	Beneficial owner	[REDACTED] (Unlisted Shares)	[REDACTED]	[REDACTED]
			[REDACTED] (H Shares)	[REDACTED]	[REDACTED]
Dr. Hu Tianwen (胡天文)	Executive Director and deputy general manager	Beneficial owner	[REDACTED] (H Shares)	[REDACTED]	[REDACTED]
Dr. Yang Rulei (楊汝磊)	Chairman of the Supervisory Committee	Beneficial owner	[REDACTED] (H Shares)	[REDACTED]	[REDACTED]
Mr. Li Jian (李建)	Supervisor (employee’s representative)	Beneficial owner	[REDACTED] (H Shares)	[REDACTED]	[REDACTED]

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

2. Substantial Shareholders

For the information on the persons who will, immediately following the completion of the [REDACTED], have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to our Company and the Hong Kong Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, please see the section headed “Substantial Shareholders” in this document.

Save as set out above and Mr. Jiang Xiangrui (蔣翔銳), being a substantial shareholder of Nantong Hefeng with 49% equity interest in Nantong Hefeng, our Directors are not aware of any other person (other than our Directors, Supervisors or chief executive) will, immediately following completion of the [REDACTED], directly or indirectly, be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Company.

3. Service Contracts

Each of our Directors and Supervisors has entered into a service contract or a letter of appointment with our Company. The principal particulars of these service contracts comprise termination provisions in accordance with their respective terms. Our Directors may be re-appointed subject to Shareholders’ approval.

Save as disclosed above, none of our Directors and Supervisors has or is proposed to have entered into any service contract with any member of our Group (excluding contracts expiring or determinable by any member of our Group within one year without payment of compensation other than statutory compensation).

4. Remuneration of Directors and Supervisors

Save as disclosed in the section headed “Directors, Supervisors and Senior Management” and “Appendix I — Accountants’ Report” for the financial year ended December 31, 2023 and the nine months ended September 30, 2024, none of our Directors or Supervisors received other remunerations of benefits in kind from us.

5. Disclaimers

- (a) save as disclosed in this document, none of our Directors, Supervisors and the parties listed in “— Other Information — 5. Qualifications of Experts” of this Appendix is:
 - (i) interested in our promotion, or in any assets which have been, within two years immediately preceding the date of this document, acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to any member of our Company; or

APPENDIX VII STATUTORY AND GENERAL INFORMATION

The Sole Sponsor satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of Listing Rules.

The Sole Sponsor will receive a fee of US\$600,000 to act as a sponsor to our Company in connection with the [REDACTED].

4. Preliminary expenses

As of the Latest Practicable Date, our Company has not incurred material preliminary expenses.

5. Qualification of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given opinions and/or advice in this document are as follows:

<u>Name</u>	<u>Qualifications</u>
CITIC Securities (Hong Kong) Limited	Licensed corporation to conduct Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities under the SFO
Deloitte Touche Tohmatsu	Certified public accountants
JunHe LLP	Company’s PRC Legal Adviser
Jingtian & Gongcheng	Company’s legal adviser as to PRC intellectual property laws
China Insights Industry Consultancy Limited	Independent industry consultant
AVISTA Valuation Advisory Limited	Property Valuer

6. Consents

Each of the experts as referred to in the paragraph headed “— Other Information — Qualifications of Experts” of this Appendix has given and has not withdrawn its respective written consents to the issue of this document with the inclusion of certificates, letters, opinions or reports and the references to its name included herein in the form and context in which it respectively included.

APPENDIX VII STATUTORY AND GENERAL INFORMATION

7. Taxation of Holders of H Shares

(1) *Hong Kong*

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.1% of the consideration or, if higher, the fair value of the H Shares being sold or transferred. For further details in relation to taxation, see “Appendix IV — Taxation and Foreign Exchange” to this document.

(2) *Consultation with professional advisers*

Potential [REDACTED] in the [REDACTED] are urged to consult their professional tax advisers if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of or dealing in our H Shares (or exercising rights attached to them). None of our Company, our Directors, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED] or any other person or party involved in the [REDACTED] accept responsibility for any tax effects on, or liabilities of, any person, resulting from the subscription, purchase, holding or disposal of, dealing in or the exercise of any rights in relation to our H Shares.

8. No Material Adverse Change

Our Directors confirm that, as of the date of this document, there has been no material adverse change in the financial or trading position of our Company since September 30, 2024 (being the latest balance sheet date of our condensed consolidated financial statements).

9. Promoters

The promoters of our Company are all then 18 shareholders of our Company as of April 28, 2023, before our conversion into a joint stock company with limited liability. Save as disclosed in this document, within the two years preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any promoter in connection with the [REDACTED] and the related transactions described in this document.

10. Restriction on Repurchase

For details, see “Appendix V — Summary of Principal Legal and Regulatory Provisions” and “Appendix VI — Summary of the Articles of Association” to this document.

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

11. Binding Effect

This document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

12. Bilingual Document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided under section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

13. Miscellaneous

Save as otherwise disclosed in this document:

- (a) within the two years preceding the date of this document, (i) our Company has not issued nor agreed to issue any share or loan capital fully or partly paid either for cash or for a consideration other than cash; and (ii) no commission, discount, brokerage or other special term has been granted in connection with the issue or sale of any shares of our Company;
- (b) no Share or loan capital of our Company or any of our subsidiaries, if any, is under option or is agreed conditionally or unconditionally to be put under option;
- (c) our Company has not issued nor agreed to issue any founder shares, management shares or deferred shares;
- (d) our Company has no outstanding convertible debt securities or debentures;
- (e) there is no arrangement under which future dividends are waived or agreed to be waived;
- (f) there has been no interruption in our business which may have or have had a significant effect on the financial position in the last 12 months;
- (g) our Company is not presently listed on any stock exchange or traded on any trading system; and
- (h) our Company is a joint stock limited company and is subject to the PRC Company Law.

**APPENDIX VIII DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (i) a copy of each of the material contracts referred to in the paragraph headed “Appendix VII — Statutory and General Information — B. Further Information about the Business of our Company — 1. Summary of Material Contracts” in this document; and
- (ii) the written consents referred to in the paragraph headed “Appendix VII — Statutory and General Information — D. Other Information — 6. Consents” in this document.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Hong Kong Stock Exchange at www.hkexnews.hk and our website at www.vigonvita.cn during a period of 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the accountants’ report prepared by Deloitte Douche Tohmatsu, the text of which is set out in Appendix I to this document;
- (c) the audited consolidated financial statements of our Company for the year ended December 31, 2023 and the nine months ended September 30, 2024;
- (d) the report prepared by Deloitte Douche Tohmatsu on the unaudited [REDACTED] financial information of our Company, the text of which is set out in Appendix II to this document;
- (e) the industry report issued by China Insights Consultancy referred to in the section headed “Industry Overview” in this document;
- (f) the PRC legal opinion issued by JunHe LLP, our legal advisors as to PRC law, in respect of, among other things, the general matters of our Company under the PRC laws;
- (g) the property valuation report prepared by AVISTA Valuation Advisory Limited, the text of which is set out in Appendix III to this document;
- (h) the material contract referred to in the paragraph headed “Appendix VII — Statutory and General Information — B. Further Information about the Business of our Company — 1. Summary of Material Contract” in this document;

**APPENDIX VIII DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

- (i) the service contracts and letters of appointment referred to in the paragraph headed “Appendix VII — Statutory and General Information — C. Further Information about Our Directors, Supervisors and Substantial Shareholders — 3. Service Contracts” in this document;

- (j) the written consents referred to in the paragraph headed “Appendix VII — Statutory and General Information — D. Other Information — 6. Consents” in this document;
and

- (k) the PRC Company Law, the PRC Securities Law and the Oversea Listing Trial Measures together with unofficial English translations thereof.