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.

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

Abbreviations: 1L = first-line; N/A = not applicable; 5-HTT = serotonin transporter; 5-HT_3 = 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.

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.

- ***LV232***. LV232 is a potential first-in-class dual-target 5-HTT/5-HT_3 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.

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

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.

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.

- ***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.

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.

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 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.

  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 $\leq$ 2 in severity and no serious adverse events or Grade $\geq$ 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.

- *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-HT_3 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-HT_3 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.

- *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.

- *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.

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.

- ***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.

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.

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 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.

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.

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.

- ***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.

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.

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-HT_3 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.

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 dapoextine 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.

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:

Abbreviations: 1L = first-line; N/A = not applicable; 5-HTT = serotonin transporter; 5-HT_3 = 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.

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.

Packaging of 民得維®

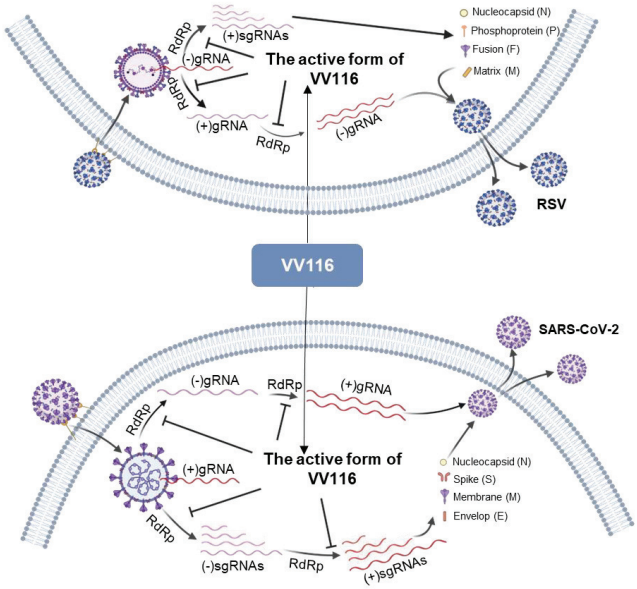
Packaging of MINDVY®

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

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."

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.

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.

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

events (occurring in ≥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

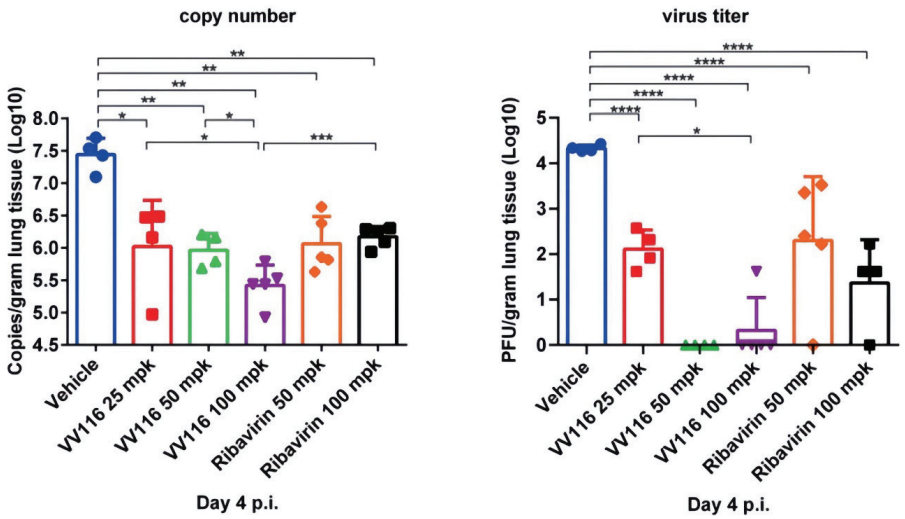
Currently, no effective antiviral treatments for RSV have been approved for marketing in China. Also, the latest Expert Consensus on the Diagnosis, Treatment, and Prevention of RSV Infections in Children does not recommend the routine use of ribavirin. As a result, there is an urgent clinical need for 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.

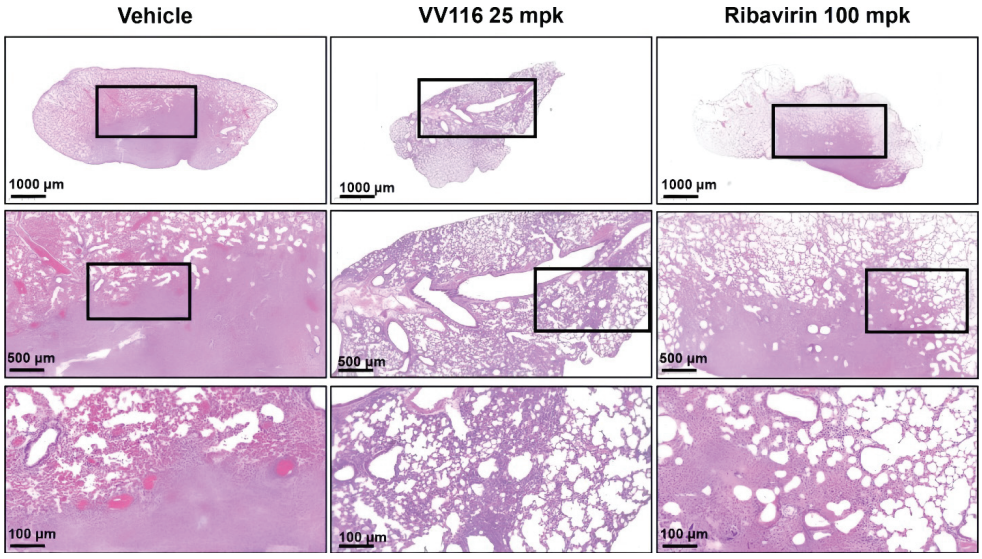
In the Balb/c mouse model, VV116 at doses of 25, 50, and 100 mg/kg significantly reduced the viral RNA copy numbers and viral titers in the lungs of mice. At a dose of 50 mg/kg, VV116 was able to reduce the viral titer to below the detection limit and showed significant improvement in the pathological changes of the lungs.

Efficacy of VV116 Against RSV Infection in Balb/c Mice

(A)



(B)



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.

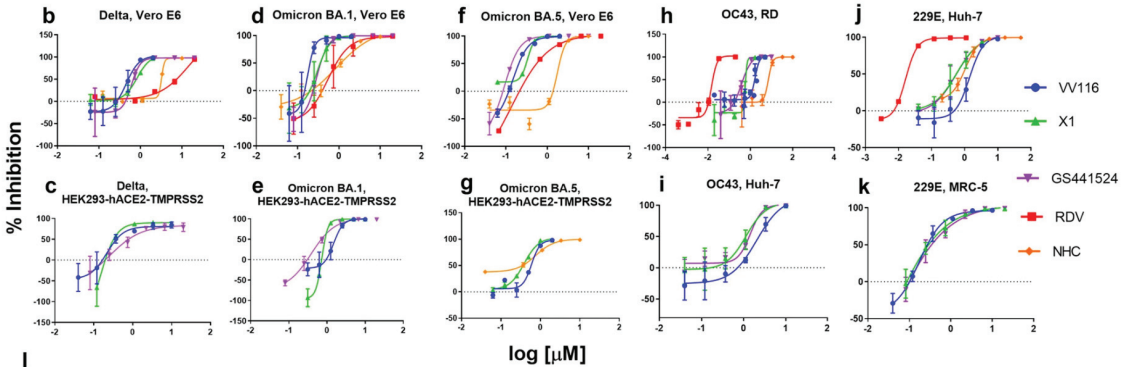
In a completed Phase I clinical study conducted in healthy adult individuals in China, data demonstrated that co-administration of VV116 dry suspension with infant formula did not significantly affect the bioavailability of 116-N1. The trial also confirmed VV116's favorable safety profile, with all adverse drug reactions being Grade $\leq$ 2 in severity and no serious adverse events or Grade $\geq$ 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.

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:

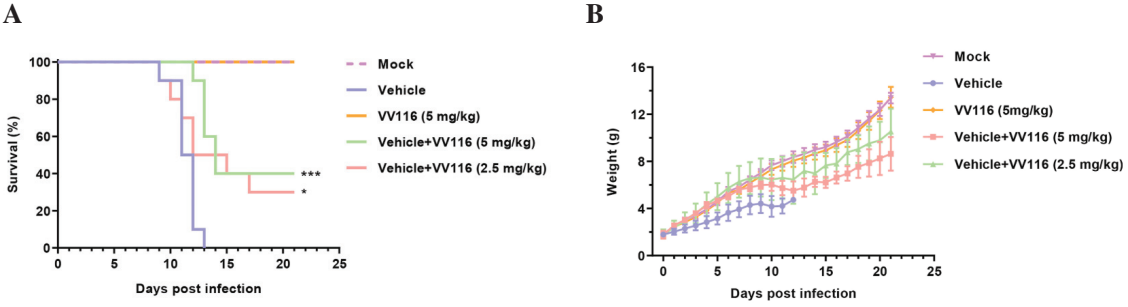
- X1 refers to VV116's parent nucleoside
- GS441524 refers to main plasma metabolite of the antiviral prodrug remdesivir
- RDV refers to remdesivir
- NHC refers to β-d-N4-hydroxycytidine

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.

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.

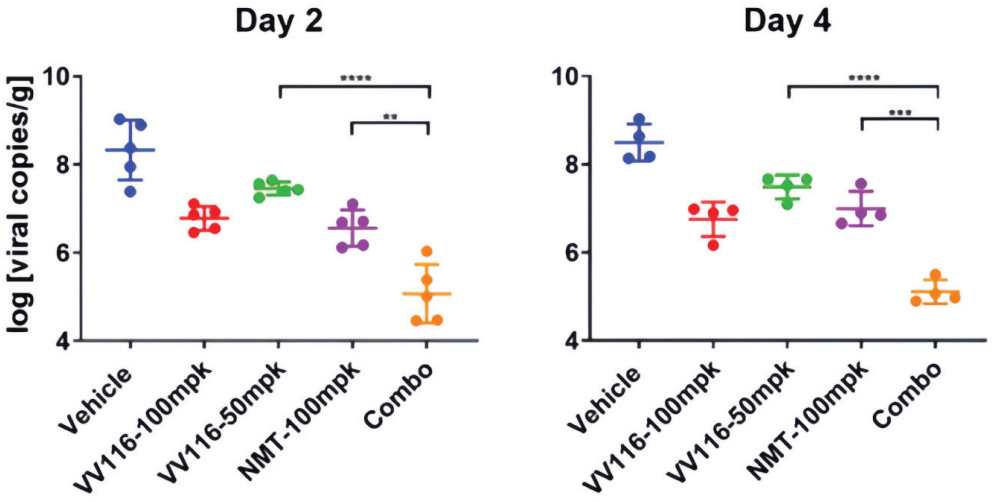
$*P < 0.05$ and $***P < 0.001$.

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.

***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.

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

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 ≥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)
	no. of patients (%)	
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:

1. 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.

2. 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

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 endpoint[1]		
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. 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)

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).

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 ≥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).

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.

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.

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.

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.

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.

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-HT_3 Receptor Modulator

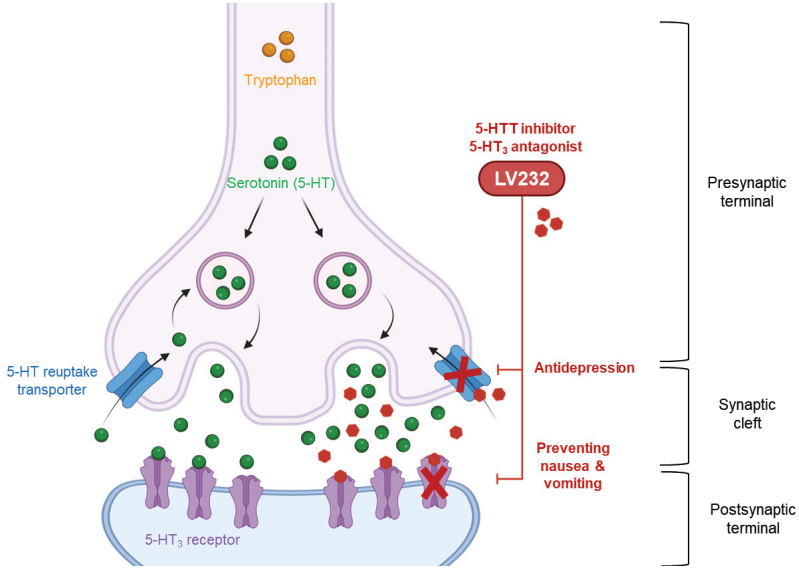
LV232 is a potential first-in-class, dual-target drug inhibiting 5-HTT and antagonizing 5-HT_3 receptor for the treatment of depression. The two targets of LV232 work synergistically, enhancing the antidepressant effects while reducing the severity of common gastrointestinal side effects such as nausea 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-HT_3 receptor. By antagonizing the 5-HT_3 receptor, it can reduce common side effects such as nausea and vomiting associated with selective serotonin reuptake inhibitors.



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

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-HT_3 receptor, was the only product exclusively targeting both the 5-HTT and 5-HT_3 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

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.

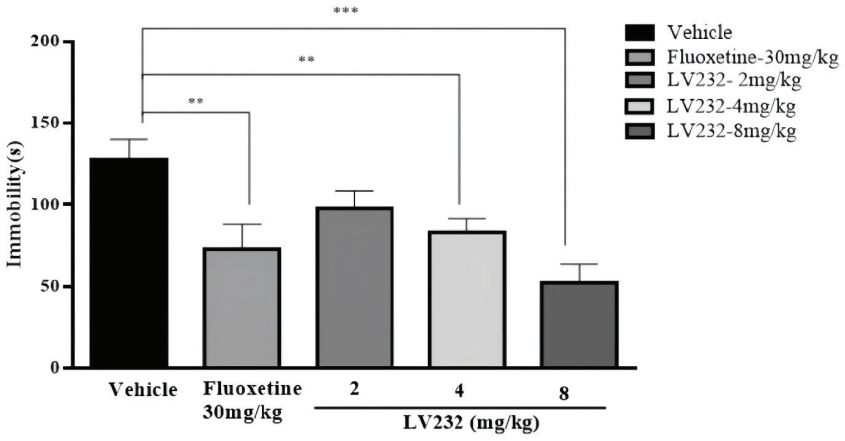
Encouraging Efficacy Profile Based on Preclinical Studies

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 an 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.

Forced Swim Test in C57BL/6J Mice



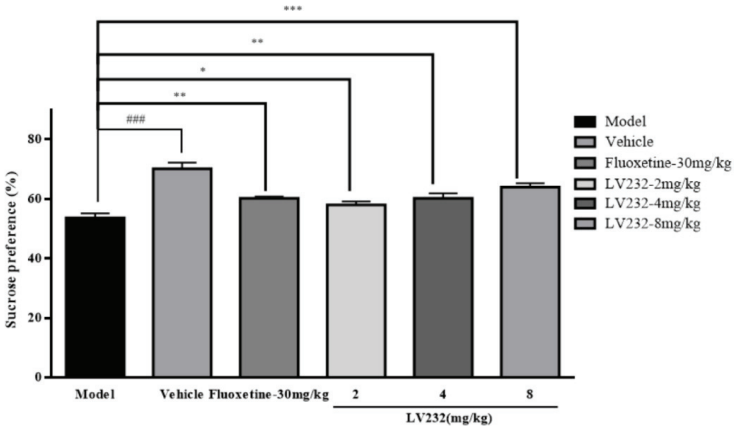
Note: Compared to the Vehicle group: *p<0.05, **p<0.01, ***p<0.001.

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.

Sucrose Preference Test After 28 Days of Administration



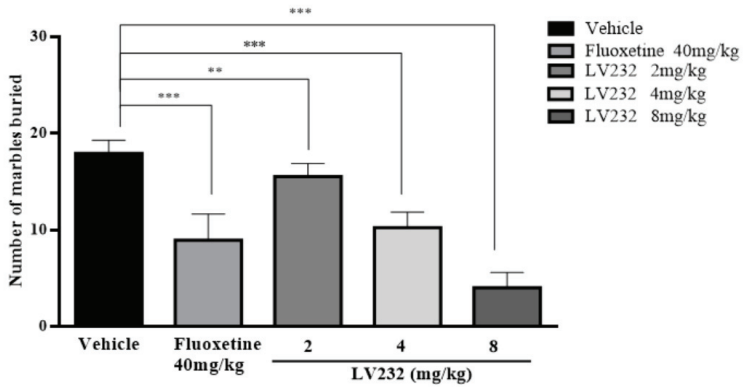
Note: Comparison between the drug group and the model group: *p<0.05, **p<0.01, ***p<0.001; comparison between the model group and the vehicle group: ###p<0.001.

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.

Marble Burying Test in C57BL/6J Mice



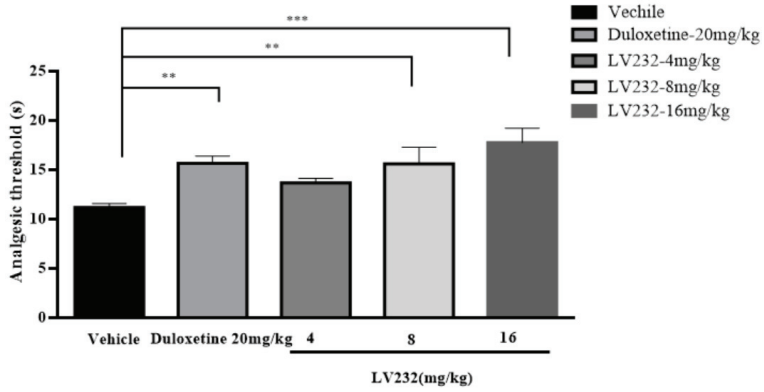
Note: *p<0.05, **p<0.01, ***p<0.001

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

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.

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.

- **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 ≥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 ≥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.

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

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®

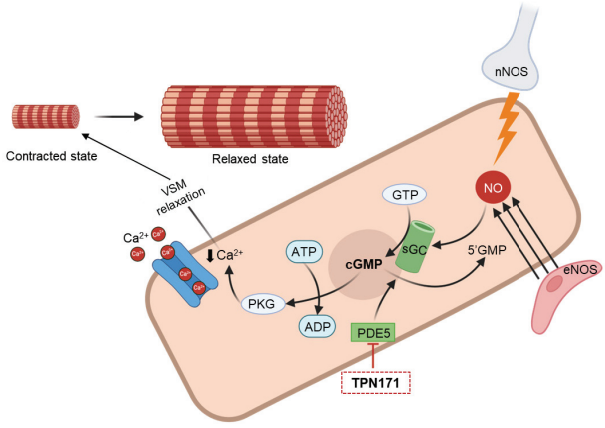
Source: Company data

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.

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.

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 IC_{50} 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

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

	TPN171		sildenafil		tadalafil	
PDEs	**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 IC_{50}(PDEs)/IC_{50}(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.

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%	33%
		20mg	8.0	21%	29%
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

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.

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 ≥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 ≥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.

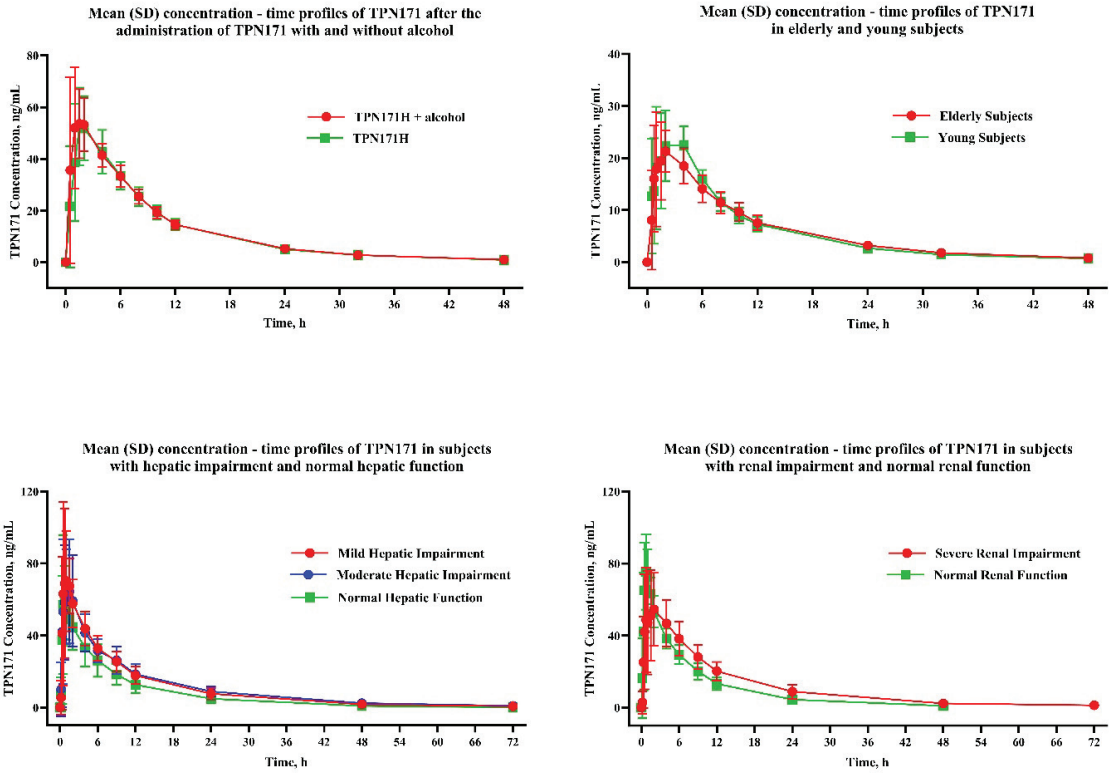
Source: Company data

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 elderlies, as well as those with mild to moderate liver impairment or mild to severe renal impairment, do not require dosage adjustments.

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.

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 SADRs 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.

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.

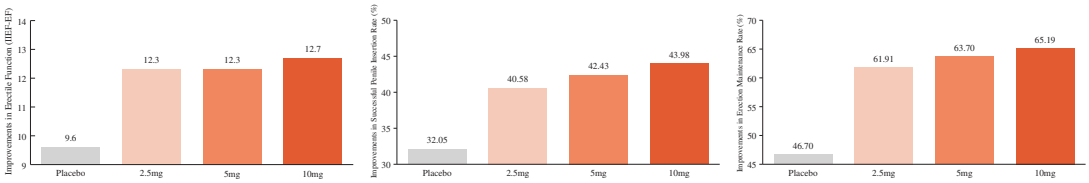
Trial Status. This trial was initiated in December 2021, the last patient's last visit was completed in February 2023, and the study was completed in June 2023.

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.

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.

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.

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."

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

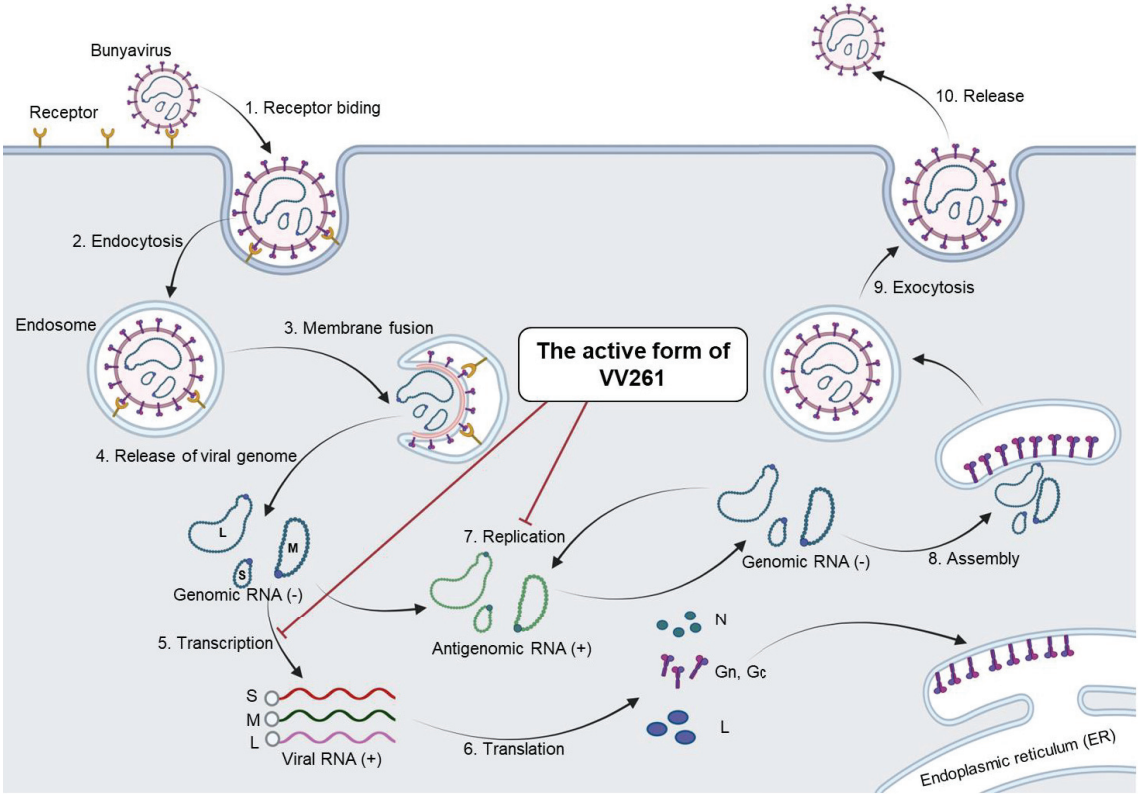
VV261 is a broad-spectrum antiviral nucleoside prodrug targeting RdRp of viruses. Once administered, it is converted into its active nucleoside triphosphate form, which inhibits the RdRp of the SFTSV, disrupting the virus' transcription and genome replication processes to effectively treat SFTSV infection. 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.

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 Bunyavirales 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

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.

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.

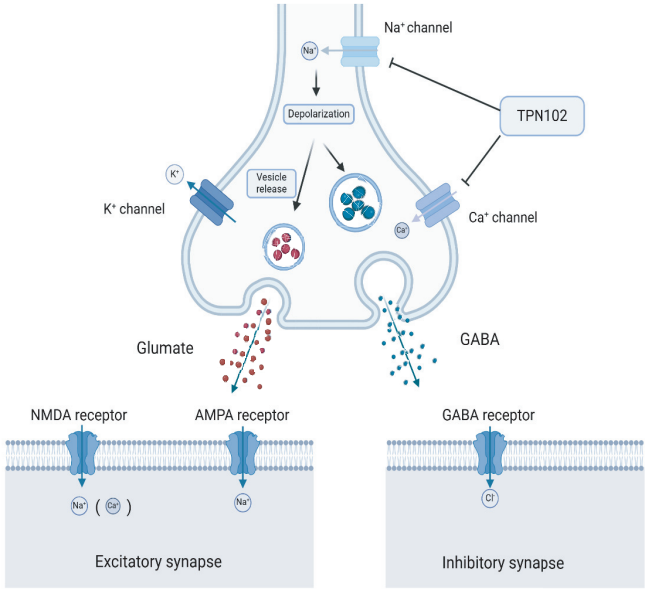
We have obtained IND approval for conducting Phase I and Phase II clinical trials of TPN102 for the treatment of epilepsy from the NMPA in June 2018. As of the Latest Practicable Date, TPN102 was in the Phase I clinical stage.

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

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."

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 in 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.

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

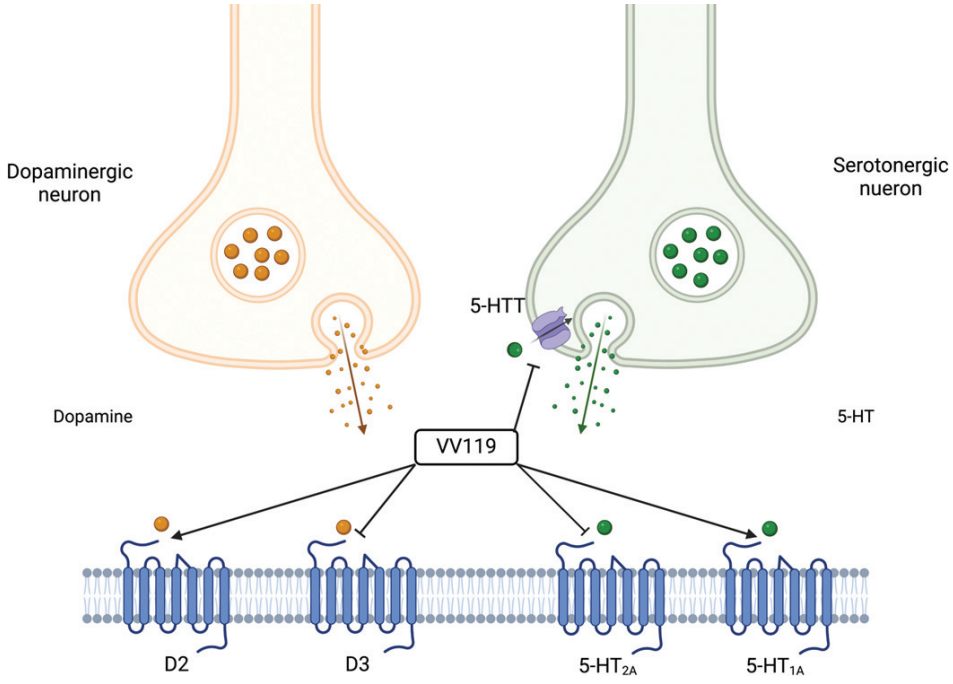
VV119 is an internally discovered, multi-target serotonin-dopamine activity modulator for the treatment of psychiatric disorders, especially schizophrenia. As a prodrug, VV119 and its major active metabolite can act through a combination of antagonistic activity at the D_3 receptor, partial agonistic activity at the D_2 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.

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 D_2 receptor, thereby preventing both excessive activation and complete blockade of these receptors. In addition, it antagonizes dopamine D_3 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.

Antipsychotic drugs are the preferred treatment for schizophrenia. They can be generally divided into conventional and atypical drugs. Conventional antipsychotic drugs primarily target D_2 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.

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 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.

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.

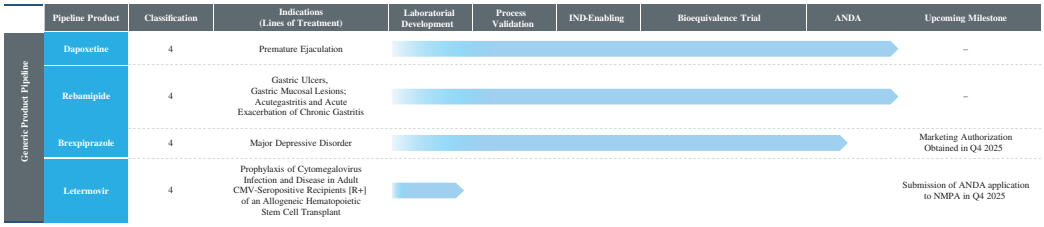
We co-discovered VV913 with Independent Third Party partners. We acquired their respective shares of rights in 2023 and we maintain the exclusive global rights to research, development, manufacture and commercialize VV913. As of the Latest Practicable Date, VV913 was under preclinical studies. We expect 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:



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).

- **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.

- **Brexpiprazole** is a 5-HT/DA activity modulator that exhibits partial agonist activity at the 5-HT_{1A} and D_2 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.

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.

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.

- 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.

- 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.

Intellectual Property Arrangements

- 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.

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.

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	• We acquired exclusive rights to research, develop, manufacture, and commercialize LV232 for all potential indications worldwide.
Allocation of Responsibilities	• 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	• 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	• 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.

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 Assigors 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.

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.

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.

- 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.

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, phosphodiesters, 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.

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-HT_3 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.

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.

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.

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).

- 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.

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% an 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.

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.

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	• 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	• Application for pre-IND communication • Submission of IND application
Phase I clinical trials	• Human PK and drug tolerance evaluation trials
Phase II clinical trials	• Preliminary exploration on the therapeutic efficacy • Dosage finding for phase III clinical trials
Phase III clinical trials	• Confirmation of the therapeutic efficacy and safety
NDA	• 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	• Marketing approval from the NMPA for new drug registration is obtained; new drug certificate and drug approval number are granted • Mass production commences

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

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)]
	(10,000 pills)	*(10,000 pills)*	*(%)*
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.

Expansion Plan

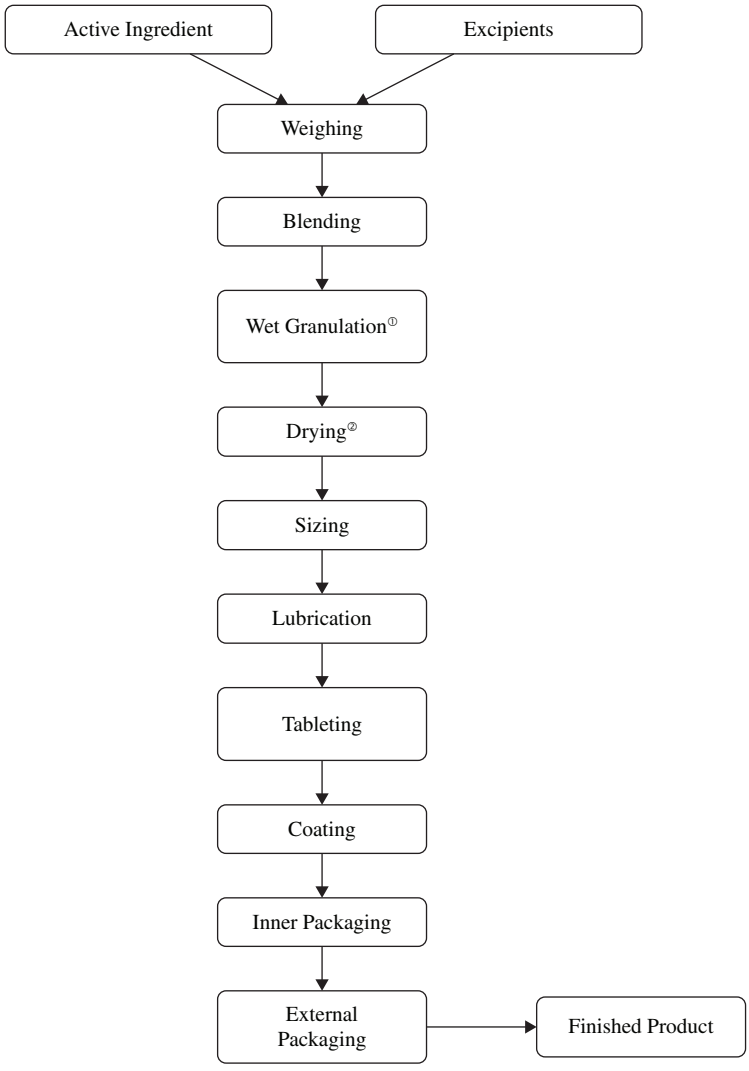
Considering the favorable support from local government, we are in the process of establishing a new manufacturing facility in Qingdao ("**Qingdao Facility**") in accordance with international GMP standards. With a GFA of approximately 11,272 sq.m., this new manufacturing facility is expected to support 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.

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.



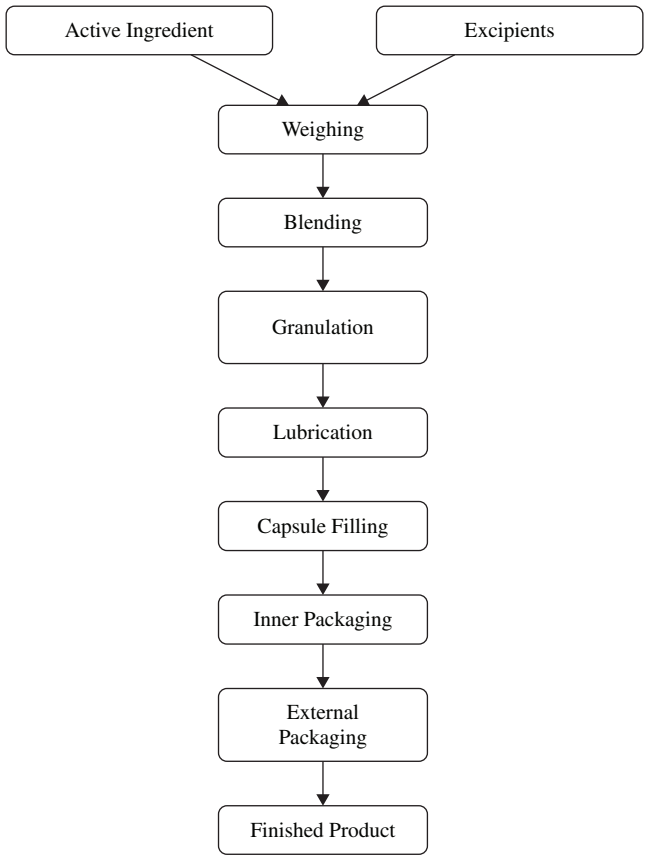
Notes:

(1) Not required for dapoxetine hydrochloride tablets;

(2) Not required for dapoxetine hydrochloride tablets.

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."

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.

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.

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.

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.

- ***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.

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.

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

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."

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

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."

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
					(RMB'000)	*(%)*
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.

Five Largest Customers for the Nine Months Ended September 30, 2024	Customers' Background	Products/Services Provided	Commencement of Business Relationship	Credit Term	Revenue Contribution	Percentage of Total Revenue
					(RMB'000)	*(%)*
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.

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. (山東特弢曼藥業有限公司)	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

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 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	Percentage of Total Purchase
					(RMB'000)	*(%)*
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

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.

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、國家税務總局江蘇省税務局)
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)

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.

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.

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.

Function	Number of employees	Percentage
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	72	25.6%
Total	**281**	**100.0%**

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.

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:

No.	Location	Usage	GFA	End of Lease Term
			(Approximate sq.m.)	
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.

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:

License/Permit	Issuing Authority	Holder	Grant date	Expiration date
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."

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.

- 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.

- 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.