
SUMMARY

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read this document in its entirety before you decide to [REDACTED] in the [REDACTED]. There are risks associated with any [REDACTED]. Some of the risks involved in [REDACTED] in the [REDACTED] are set out in the “Risk Factors” section of this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules as we do not meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies like ours. Your [REDACTED] decision should be made in light of these considerations.

OVERVIEW

We are an integrated and innovative biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs to address medical needs in oncology, immunology and other therapeutic areas in China and globally. As of the Latest Practicable Date, we were advancing a differentiated and clinically valuable pipeline of 33 assets, including five in pivotal trial or NDA registration-stage, nine in phase 1 or phase 2 stage and four in IND-enabling stage. We have two ADC drugs as our Core Products, namely, SKB264 and A166. SKB264 is a novel phase 3-stage TROP2 ADC positioned as a late-line monotherapy and part of early-line combination therapies for treating various advanced solid tumors, including breast cancer (BC), non-small cell lung cancer (NSCLC) and other major cancers. A166 is a differentiated NDA registration-stage HER2 ADC positioned as a late-line monotherapy to treat advanced HER2+ solid tumors.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR PIPELINE PRODUCTS, INCLUDING CORE PRODUCTS SKB264 AND A166.

The pipeline chart below summarizes the development status of our clinical-stage drug candidates and selected preclinical assets.

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Supported by three in-house developed technology platforms with proprietary know-how in ADCs, biologics (monoclonal antibodies (mAbs) and bispecific antibodies (bsAbs)) and small molecule drugs and validated by our clinical-stage drug candidates, our pipeline is diverse and synergistic in drug modalities, mechanisms, and indication coverage. Notably, we are one of the first movers and a leading developer of antibody drug conjugates (ADCs), with over a decade of accumulated experience in ADC development. We are one of the first biopharmaceutical companies in China, and one of the few globally, to establish an integrated ADC platform, *OptiDC*. Our drug development capabilities are further bolstered by current good manufacturing practice (cGMP)-compliant, end-to-end manufacturing capabilities and a comprehensive quality control system. Furthermore, we are well-positioned to expand our commercialization infrastructure and market access, leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network.

The clinical value of our pipeline and our drug development capabilities are recognized by the strategic partnerships we have forged worldwide to unlock the global market potential of key assets. To date, we have entered into nine out-license agreements, including three license and collaboration agreements with Merck Sharp & Dohme LLC (together with its affiliates, “MSD”) to develop up to nine ADC assets for cancer treatment with upfront and milestone payments totaling up to US\$11.8 billion. According to Frost & Sullivan, we are the first China-based company to license internally discovered and developed ADC candidates to a top-ten biopharmaceutical MNC. Our collaboration with MSD to develop up to seven preclinical ADC assets is the largest biopharmaceutical out-license deal to date secured by a China-based company, according to Frost & Sullivan, and the world’s largest biopharmaceutical partnership in terms of deal value in 2022, according to Nature Reviews Drug Discovery. We have also entered into collaboration and license agreements with Ellipses for A400, and with Harbour BioMed for A167 and SKB378. Our strategic partnerships are not only testaments to our R&D and business development capabilities, but also key drivers of our continued innovation, global influence and long-term growth.

Going forward, we strive to advance our pipeline towards commercialization and enhance our integrated drug development capabilities. We will continue to lead the R&D and clinical activities of our drug candidates, including, for assets out-licensed to our strategic partners, in the regions where we retain the rights to their development and commercialization. In addition, we are dedicated to optimizing our R&D platforms and developing novel technologies to support the R&D of innovative drugs. We will also continue to expand our cGMP manufacturing and quality control facilities, and enhance our in-house commercialization functionalities, to support the future launch of our pipeline assets and our goal to become a leading global biopharmaceutical company.

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OUR PIPELINE

Our pipeline targets the world’s prevalent or hard-to-treat cancers, such as BC, NSCLC, gastrointestinal (GI) cancers (including gastric cancer (GC) and colorectal cancer (CRC)), as well as non-oncology diseases and conditions affecting a large and underserved population. As of the Latest Practicable Date, we had established a pipeline of 14 clinical-stage drug candidates, including five in pivotal trial- or NDA registration-stage. All of these drug candidates were self-developed by the Group, other than the development that is being conducted with license and collaboration partners, as disclosed in more detail below. We have also assembled a diverse portfolio of preclinical assets, including four in IND-enabling stage, to further enrich our expanding pipeline targeting medical needs.

Our oncology franchise features diversified treatment modalities and targets different mechanisms to comprehensively treat prevalent or hard-to-treat cancers in China and worldwide, anchored by the following assets:

- **SKB264 (*sacituzumab tirumotecan*)**, one of our Core Products, is a novel TROP2 ADC targeting advanced solid tumors. Drugs that successfully target TROP2 have vast market potential as TROP2 is frequently overexpressed across a broad spectrum of cancers, especially in highly prevalent or hard-to-treat cancers such as BC, NSCLC, GC and OC. Notably, TROP2 has one of the highest overexpression rates in the lead indications of SKB264, namely BC (80%) and NSCLC (64% to 75%). BC is the most prevalent type of cancer worldwide, with TNBC and HR+/HER2- BC being the most aggressive and most prevalent subtype, respectively. Lung Cancer (LC) is the second most common cancer and the leading cause of cancer death worldwide, with NSCLC being most common subtype representing over 85% of all LC cases globally.

The global TROP2 ADC market is expected to increase from US\$0.7 billion in 2022 to US\$25.9 billion by 2030, representing a CAGR of 57.6%, while the TROP2 ADC market in China following the NMPA approval of the first TROP2 ADC in June 2022, is projected to grow from RMB0.2 billion in 2023 to RMB23.6 billion by 2030 at a CAGR of 103.0%. For more quantitative information on the drug market size, the number of patients targeted by SKB264 and the life expectancy of such patients, see “Business – Our Pipeline – Oncology Franchise – SKB264 – Market Opportunity and Competition.”

Positioned to be the first domestically developed TROP2 ADC in China, SKB264 utilizes a differentiated drug design to improve ADC stability and maintain ADC bioactivity, thus enhancing its targeting ability and reducing its off-target and on-target off-tumor toxicity, potentially leading to a broader therapeutic window. SKB264 also demonstrated encouraging efficacy across multiple types of heavily pretreated advanced solid tumors and a potentially favorable safety profile based on preliminary clinical data from its global phase 1/2 trial. We are also exploring SKB264’s early-line potential in combination therapy. Other than SKB264, Gilead Sciences’ Trodelvy, the only approved TROP2 ADC globally, and Daiichi Sankyo’s DS-1062 were the only two TROP2 ADCs in phase 3 or beyond that target the same lead indications (TNBC, HR+/HER2- BC and NSCLC) as SKB264 as of the Latest

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Practicable Date. Trodelvy is positioned as a 3L+ monotherapy for TNBC and HR+/HER2- BC, and part of a 1L combination therapy for NSCLC, while DS-1062 is positioned as a 1L monotherapy for TNBC, 2L+ monotherapy for NSCLC and HR+/HER2- BC, and part of 1L combination therapies for these three indications.

Supported by its promising proof-of-concept results, SKB264 was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. In May 2022, we granted MSD exclusive development and commercialization rights for SKB264 outside Greater China. See “Business – Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for SKB264” for details.

We are actively advancing a multi-strategy clinical development plan to explore SKB264’s potential as a monotherapy and combination therapies to treat various advanced solid tumors, including BC, NSCLC and other major cancers. For details, see “Business – Our Pipeline – Oncology Franchise – ADCs – SKB264 – Clinical Development Plan.”

- **A166 (*trastuzumab botidotin*)**, another Core Product, is a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors. It is positioned to target multiple cancer indications with high prevalence and medical needs, with the potential to be one of the first domestically developed ADCs for HER2-positive (HER2+) BC in China. HER2 overexpression is widely recognized as a major driver of prevalent cancers, including BC and GI cancers, with A166’s lead indication, advanced HER2+ BC, being a major BC subtype.

China’s HER2 ADC market is expected to grow from RMB0.6 billion in 2022 to RMB8.4 billion in 2030 at a CAGR of 38.2%. For more quantitative information on the drug market size, the number of patients targeted by A166 and the life expectancy of such patients, see “Business – Our Pipeline – Oncology Franchise – A166 – Market Opportunity and Competition.”

Configured with a potent cytotoxic payload, clinically proven mAb and site-specific conjugation technology, A166 demonstrated promising efficacy in heavily pre-treated advanced HER2+ BC patients and in advanced HER2+ GC patients and a differentiated safety profile, based on preliminary results from our ongoing phase 1 dose expansion study and ongoing phase 1b trial in China. A166 has met the primary endpoints of its pivotal phase 2 trial for advanced HER2+ BC based on results from the primary analysis, which we used to submit an NDA to the NMPA in May 2023. In addition to our pivotal phase 2 trial for advanced HER2+ BC, we are exploring the therapeutic potential of A166 in multiple phase 1b clinical trials in China for other advanced HER2+ solid tumors, including GC and CRC. As of the Latest Practicable Date, there were two approved HER2 ADCs, Genentech’s Kadcyla and Daiichi Sankyo’s Enhertu, that target the same lead indication (advanced HER2+ BC) as A166 in China, with Kadcyla positioned as a 2L treatment and Enhertu as a 2L+ treatment.

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- **SKB315** is a novel CLDN18.2 ADC targeting advanced solid tumors. As of the Latest Practicable Date, there were no CLDN18.2-targeting therapies approved globally. Due to its selective expression in prevalent and lethal cancers that have limited effective treatments such as GC and PC, CLDN18.2 has been a promising target pursued by multiple biopharmaceutical and biotech companies for in-house development and licensing deals. In June 2022, we out-licensed the global development and commercialization rights for SKB315, currently in phase 1a clinical trial, to MSD. With a differentiated payload-linker design and an in-house developed humanized CLDN18.2 antibody, SKB315 demonstrated encouraging efficacy and safety across various preclinical *in vivo* tumor models with heterogeneous CLDN18.2 expression, indicating its promising therapeutic potential.
- **A167 (*tagitanlimab*)**, our PD-L1 mAb, is expected to be our first commercialized product and the backbone of our immunotherapy franchise, with an NDA submitted to the NMPA for recurrent or metastatic nasopharyngeal carcinoma (RM-NPC) in November 2021 and conditional marketing approval expected in the second half of 2023 or the first half of 2024. We are actively exploring A167’s potential as an early-line treatment in combination with our ADC assets to maximize the clinical value of our oncology franchise, beginning with two ongoing phase 2 trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a first-line treatment for advanced TNBC.
- **A140**, a pivotal phase 3 biosimilar of EGFR mAb cetuximab. A140 has potential to be the first cetuximab biosimilar in China with an anticipated NDA filing in the second half of 2023, providing increased accessibility and affordability for a widely used therapeutic targeting a key pathway in many cancers, starting with rat sarcoma virus (RAS) wild-type mCRC, recurrent and/or metastatic HNSCC (RM-HNSCC) and locally advanced HNSCC (LA-HNSCC). A140 demonstrated pharmacokinetic (PK) equivalence to cetuximab in a phase 1 trial, with clinical equivalence being evaluated in a pivotal phase 3 trial.
- **A400**, a phase 1/2-stage second-generation selective RET inhibitor, is positioned to be the first domestically developed selective RET inhibitor for NSCLC, medullary thyroid cancer (MTC) and other solid tumors with a high prevalence of RET alterations. We have designed A400 with a novel proprietary molecular structure to potentially address selective RET inhibitor resistance while maintaining target selectivity, efficacy and safety with reduced manufacturing cost and difficulty. Based on preliminary results from its ongoing phase 1/2 trial, A400 demonstrated promising anti-tumor efficacy in patients with advanced RET+ solid tumors. Notably, A400 also demonstrated therapeutic potential in selective RET inhibitor-resistant patients, as well as a potentially favorable safety profile differentiated from approved first-generation selective RET inhibitors. In March 2021, we granted to Ellipses, a U.K.-based international drug development company, an exclusive license to develop, manufacture and commercialize A400 outside Greater China and certain Asian countries.

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We will also continue to accelerate the R&D of our preclinical oncology assets. For example, we are developing over ten preclinical ADC assets with their respective targets expressed across a broad spectrum of solid tumors. In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional exclusive licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for China, Hong Kong and Macau. For details, see “Business – Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for Up to Seven Preclinical ADC Assets.”

Our non-oncology franchise covers a range of diseases and conditions with large patient populations and medical needs, with a primary focus on immune-mediated diseases, including rheumatoid arthritis (RA) and alopecia areata (AA).

Our non-oncology franchise is headlined by A223, potentially one of the first small molecule JAK1/2 inhibitors developed domestically for multiple autoimmune diseases with large patient populations, including RA and AA, in China. A223 has demonstrated an encouraging safety profile in three completed trials and two ongoing trials, where most treatment-emergent adverse events (TEAEs) were mild or moderate with no incidence of black box warning-related safety issues commonly reported by approved JAK inhibitors. Based on preliminary clinical data from its phase 2 trial, A223 demonstrated promising anti-rheumatic efficacy in moderate-to-severe RA patients. These promising clinical results indicates the potential of A223 to be an effective treatment option with improved efficacy and safety for RA. Besides RA, we also target AA, a common autoimmune disease that affected approximately 4.0 million people in China in 2022.

In addition to A223, we are also evaluating three other clinical-stage assets (A277, SKB378 and SKB336) and various preclinical assets to target indications ranging from chronic kidney disease (CKD)-associated pruritus (CKD-aP), moderate-to-severe asthma, thromboembolic disorders, to other diseases and conditions with large patient populations and medical needs. Apart from our existing assets, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCTS, OR ANY OF OUR DRUG CANDIDATES.

OUR TECHNOLOGY PLATFORMS

We have established three core platforms specializing in ADC, biologics and small molecule technologies that serve as the foundation of our discovery and development of innovative medicines for medical needs in selected disease areas, such as oncology, autoimmune diseases and metabolic diseases. These platforms cover the entire R&D process for different drug modalities and are integrated to allow cross-functional synergies at crucial

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stages of drug development. Our ADC platform, *OptiDC*, is supported by three capability pillars – in-depth knowledge of biological targets and diseases, tested and verified ADC design and development know-how, and a toolbox of core ADC components. Our biologic platform serves as the foundation of our immunotherapy and targeted therapy franchises which possesses end-to-end antibody development capabilities ranging from antibody discovery and optimization to bioprocessing and scale-up manufacturing. Our small molecule platform allows us to focus on compound optimization in early-stage research, which help rationalize and accelerate our preclinical drug discovery. For details, please see “Business – Overview – Our Technology Platforms.”

OUR COMPETITIVE STRENGTHS

We believe the following competitive strengths have differentiated us from our competitors: (i) integrated ADC development platform, “*OptiDC*,” with a competitive ADC drug portfolio to address medical needs globally; (ii) comprehensive pipeline of anti-tumor drugs harnessing our multi-platform technology expertise, with strong monotherapy and combination therapy potential; (iii) well-selected non-oncology pipeline strategically targeting diseases and conditions with immense medical needs; (iv) integrated drug development capabilities across R&D, manufacturing, quality control and commercialization; (v) cross-border business development capabilities enabling collaborations and strategic partnerships; and (vi) experienced leadership backed by our Controlling Shareholder and renowned investors. For details, see “Business – Our Competitive Strengths.”

OUR DEVELOPMENT STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following development strategies: (i) advance our indication-oriented oncology pipeline; (ii) advance and expand our differentiated non-oncology drug portfolio; (iii) enhance our integrated drug development capabilities; (iv) continue to seek and deepen strategic partnerships to extend the potential of our technology platforms and maximize the value of our pipeline; and (v) optimize our integrated operation system to become a leading global biopharmaceutical company. For details, see “Business – Our Development Strategies.”

OUR INTEGRATED DRUG DEVELOPMENT CAPABILITIES

We have developed integrated capabilities encompassing all key drug development functionalities, including R&D, manufacturing, quality control and commercialization. Our drug development capabilities are governed by a well-established management system that covers all key business functionalities, which provides a framework for our internal teams to engage in constructive dialogue and evaluation, particularly when making critical decisions for each drug development plan. While we are primarily focused on the in-house development of our pipeline, we supplement our in-house efforts with a dynamic global business development strategy to maximize the commercial value of our pipeline in major international markets, leveraging our experience in forging strategic partnerships worldwide.

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Our in-house R&D capabilities, built on three technology platforms with proprietary know-how, give us control and visibility over our R&D process, reduces our reliance on CROs and enable us to ensure the quality and efficiency of our drug development programs. Our drug development capabilities are further bolstered by cGMP-compliant, end-to-end manufacturing capabilities that cover the entire development lifecycle of ADCs, including two 2,000 litre (L) single-use bioreactors, one 300 L ADC conjugation tank with a maximum annual production capacity of 40 batches of ADC drug substance and facilities for payload-linker synthesis, antibody formulation and ADC formulation, as well as a comprehensive quality control system. We are building up our commercialization infrastructure in anticipation of our late-stage drug candidates’ commercial launch in China, leveraging our Controlling Shareholder Kelun Pharmaceutical’s decades-long experience, industry connections and extensive network.

Our drug development capabilities are recognized by the breadth, depth and commercial value of the strategic partnerships we have forged worldwide, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. These landmark transactions speak to the quality and soundness of our capabilities in every key step of our ADC development process, from drug discovery to manufacturing and quality control. For details of our drug development capabilities, see “Business.”

LICENSE AND COLLABORATION ARRANGEMENTS

While we are primarily engaged in in-house drug development, we also believe that an open and collaborative mindset is crucial to the success of our global strategy. Along each step of our drug development plans – from drug discovery to commercialization – we proactively pursue external collaborations, licensing arrangements and other strategic partnerships to create synergies with our pipeline and technology platforms. Set forth below is a summary of our key license and collaboration agreements. For details, see “Business – Our License and Collaboration Arrangements.”

- **Collaboration with MSD.** To date, we have entered into three license and collaboration agreements with MSD to develop SKB264, SKB315 and up to nine ADC assets for cancer treatment. In May 2022, we granted to MSD an exclusive, royalty-bearing and sublicensable license to develop, use, manufacture and commercialize our TROP2 ADCs, including SKB264 (also known as “MK2870” in MSD’s portfolio) and any other TROP2 ADCs we may develop in the future, and products containing one or more such TROP2 ADCs outside Greater China. We retain the right to develop and commercialize SKB264 and other TROP2 ADCs within Greater China. Based on such retained rights, we will continue to advance our clinical development plan for SKB264 in Greater China.

In June 2022, we granted to MSD an exclusive, royalty-bearing, sublicensable license to develop, use, manufacture and commercialize SKB315 and products based on SKB315 globally. In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional exclusive licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for China, Hong Kong and Macau.

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- **Collaboration with Ellipses.** We granted to Ellipses an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A400, our RET inhibitor, in all countries excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand.
- **Collaboration with Harbour BioMed.** We granted to Harbour BioMed an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A167, our PD-L1 mAb, outside Greater China. We are also jointly developing SKB378, our anti-TSLP mAb, with Harbour BioMed.

OUR COMPETITIVE LANDSCAPE

We primarily compete against large multinational pharmaceutical companies, well-established biopharmaceutical companies and specialty pharmaceutical companies that have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of indications which our drug candidates also target, especially companies involved in the research and development of ADCs. The level of competition that we face is high and we believe the following aspects are critical for us to stay competitive and relevant in this dynamic environment: (i) a strong and comprehensive drug pipeline, (ii) technology platforms validated by our clinical-stage drug candidates, (iii) integrated capabilities across all key drug development functionalities, (iv) strong cross-border business development capabilities, and (v) an experienced leadership team. See also “Business – Our Competitive Strengths.”

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business, and we are committed to the development and protection of our intellectual properties. We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 74 issued patents in China, (ii) 21 issued patents in the U.S., (iii) 52 issued patents in other jurisdictions, and (iv) 255 pending patent applications, including 100 in China, 14 in the U.S., 16 under the Patent Cooperation Treaty (PCT) and 125 in other jurisdictions. With respect to our two Core Products, SKB264 and A166, we owned five issued patents in China and eight issued patents in other jurisdictions, as well as 21 pending patent applications, including six in China, five in the U.S., three under the PCT and eight in other jurisdictions, including Europe, Canada, Japan and Hong Kong as of the Latest Practicable Date. As of the Latest Practicable Date, we were patentee of all granted patents in China relating to the structure, formulation and use of SKB264 and A166, which are considered to be material aspects of each drug. The patents granted to, or under application by, our Company cover all material aspects of our Core Products. For details, please see “Business – Intellectual Property.”

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SUMMARY OF KEY FINANCIAL INFORMATION

The summary of the key financial information set forth below have been derived from and should be read in conjunction with our consolidated financial statements, including the accompanying notes, set forth in the Accountants’ Report in Appendix I to this document, as well as the information set forth in the section headed “Financial Information.”

Summary of Consolidated Statements of Profit or Loss

We recognized revenue of RMB32.3 million and RMB803.9 million, respectively, in the years ended December 31, 2021 and 2022, which was primarily in relation to the license and collaboration agreements we entered into. We incurred net losses during the Track Record Period as we invested significant capital into the research and development of our extensive drug pipeline, and building up our technology platforms, manufacturing facilities and other capabilities to complement and support our business. For the years ended December 31, 2021 and 2022, we had net losses of RMB889.8 million and RMB616.1 million, respectively. The decrease of our net losses from 2021 to 2022 was primarily due to the increase in revenue from the two license and collaboration agreements we entered into with MSD to develop SKB264 and SKB315.

The following table sets forth the summary of our consolidated statements of profit or loss and other comprehensive income for the years indicated:

	For the year ended December 31,	
	2021	2022
	<i>(RMB’000)</i>	<i>(RMB’000)</i>
Revenue	32,322	803,933
Cost of sales	(20,525)	(276,828)
Gross profit	11,797	527,105
Other net income/(expense)	34,843	(4,368)
Administrative expenses	(96,174)	(95,303)
Research and development expenses	(727,670)	(845,984)
Loss from operations	(777,204)	(418,550)
Finance costs	(112,591)	(148,814)
Loss before taxation	(889,795)	(567,364)
Income tax	–	(48,735)
Loss for the year attributable to equity shareholders of the Company	(889,795)	(616,099)

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Summary of Consolidated Statements of Financial Position

The following table sets forth a summary of our consolidated statements of financial position as of the dates indicated:

	As of December 31,	
	2021	2022
	(RMB'000)	(RMB'000)
Total non-current assets	514,617	660,829
Total current assets	298,341	332,316
Total current liabilities	3,444,914	4,167,361
Net current liabilities	(3,146,573)	(3,835,045)
Total assets less current liabilities	(2,631,956)	(3,174,216)
Total non-current liabilities	11,930	51,970
Net liabilities	(2,643,886)	(3,226,186)

We recorded net liabilities of RMB2,643.9 million and RMB3,226.2 million as of December 31, 2021 and 2022, respectively. The increase was primarily due to the loss for the year of RMB616.1 million we recorded in 2022, as a result of the significant capital we invested into the research and development of our extensive drug pipeline, and building up our technology platforms, manufacturing and other capabilities to complement and support our business.

We recorded net current liabilities of RMB3,146.6 million and RMB3,835.0 million as of December 31, 2021 and 2022, respectively, mainly attributable to bank loans and other borrowings of RMB2,388.0 million and RMB2,890.8 million, respectively, as of the same dates. These amounts primarily represented our borrowings from Kelun Pharmaceutical to support our operations. Pursuant to a share subscription and debt-to-equity swap agreement between us, Kelun Pharmaceutical and the other then Shareholders on January 3, 2023, we settled RMB2.5 billion of the outstanding balance of such borrowings by issuing equity to Kelun Pharmaceutical. As of the Latest Practicable Date, the remaining balance of our borrowings from Kelun Pharmaceutical had been repaid in full by cash. For further details, see “History and Corporate Structure – Corporate History – Establishment and Major Shareholding Changes of Our Company – 4. Series B Financing – Share Subscription by Kelun Pharmaceutical” and “Financial Information – Material Related Party Transactions.”

Despite the debt-to-equity swap and the Series B Financing, we still recorded a net current liability position of RMB947.9 million as of April 30, 2023, primarily due to the shares with preferential rights we issued to the Pre-[REDACTED] Investors. However, we expect our net current liabilities position to improve significantly upon [REDACTED], as we recorded RMB1,952.3 million in financial instruments issued to [REDACTED] as of April 30, 2023. Such shares will be converted into ordinary Shares upon [REDACTED], after which they will be recorded as equity and no longer be recorded as liabilities on our statement of financial position. As such, we expect that our net current liability and net liability position will turn into net current asset and net asset position, respectively, upon [REDACTED].

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Summary of Consolidated Statements of Cash Flows

The following table sets forth the components of our consolidated statements of cash flows for the years indicated:

	For the year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Net cash used in operating activities	(485,942)	(270,847)
Net cash used in investing activities	(94,384)	(32,150)
Net cash generated from financing activities	647,316	313,452
Net increase in cash and cash equivalents	66,990	10,455
Cash and cash equivalents at beginning of year	16,189	81,793
Effect of foreign exchange rate changes	(1,386)	712
Cash and cash equivalents at the end of year	81,793	92,960

We recorded net cash used in operating activities of RMB485.9 million and RMB270.8 million for the years ended December 31, 2021 and 2022, respectively, primarily due to investments in our research and development activities. During the Track Record Period, we financed our operations primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with our license and collaboration agreements, and proceeds from Series A Financing. As of April 30, 2023, the latest practicable date for determining our indebtedness, we had cash and cash equivalents of RMB1,342.2 million.

We expect to fund our future operations primarily with existing cash and cash equivalents, payments received from our license and collaboration agreements, and [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. As our business continues to expand, we may require further funding through equity offerings, debt financing, license and collaboration arrangements, and other sources.

Although we recorded significant net current liabilities during the Track Record Period, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses (including any production costs), for at least the next 12 months from the date of this document, taking into account (i) the recent settlement of borrowings from Kelun Pharmaceutical, as a result of which our net current liabilities decreased to RMB947.9 million as of April 30, 2023, (ii) the capital resources available to fund our operations, including existing cash and cash equivalents, payments received from our license and collaboration agreements and [REDACTED] from the [REDACTED], and (iii) our cash burn rate, which is the average monthly amount of net cash used in operating activities, payment for property, plant and equipment and payment for intangible assets. For details, see “Financial Information – Liquidity and Capital Resources – Working Capital Sufficiency.”

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Key Financial Ratios

The following table set forth our key financial ratios⁽¹⁾ as of the dates:

	As of December 31,	
	2021	2022
Current ratio (%)	8.7	8.0
Quick ratio (%)	7.2	6.7

Note:

(1) For details, see “Financial Information – Key Financial Ratios.”

Cash Operating Costs

The following table provides information regarding our cash operating costs for the years indicated:

	For the year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Costs relating to research and development of our Core Products		
Staff cost	51,085	109,369
Trial and testing expenses	61,769	89,665
Raw materials and others	15,046	57,256
<i>Subtotal</i>	127,900	256,290
Costs relating to research and development of our other drug candidates		
Staff cost	183,071	184,013
Trial and testing expenses	143,068	289,284
Raw materials and others	53,211	58,135
<i>Subtotal</i>	379,350	531,432
Total	507,250	787,722

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	For the year ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Workforce employment costs ⁽¹⁾	74,258	62,490
Direct production costs ⁽²⁾	–	–
Product marketing ⁽³⁾	–	–
Non-income taxes, royalties and other governmental charges	–	–
Contingency allowances	–	–

Notes:

- (1) Workforce employment costs represent total non-research and development personnel costs mainly including salaries and benefits.
- (2) We had not commenced commercial-scale product manufacturing as of the Latest Practicable Date.
- (3) We had not commenced product sales as of the Latest Practicable Date.

SUMMARY OF MATERIAL RISK FACTORS

Our business faces risks including those set out in the section headed “Risk Factors.” As different [REDACTED] may have different interpretations and criteria when determining the significance of a risk, you should read the “Risk Factors” section in its entirety before you decide to [REDACTED] in our Company. Some of the major risks that we face include: (i) our business and prospects depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected; (ii) we may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates; (iii) we have incurred significant net losses since inception. We anticipate that we will continue to incur net losses and may fail to achieve or maintain profitability in the future; (iv) we have entered into license and collaboration agreements with third parties in the development of our drug candidates, and may seek additional licensing and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected; (v) if we are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize our drug candidates may be adversely affected; (vi) the future commercial success of our drug candidates will depend on the degree of their market acceptance among physicians, patients and others in the medical community; and (vii) our future success depends in part on our ability to retain our senior management, scientific employees and other qualified personnel.

SUMMARY

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Kelun Pharmaceutical was directly interested in approximately 59.75% of the total issued Shares of our Company. In addition, our Employee Incentive Platforms, namely Kelun Huicai, Kelun Huineng, Kelun Huizhi and Kelun Huide, were directly interested in approximately 15.52% of the total issued Shares of our Company. Kelun Jingchuan, a wholly-owned subsidiary of Kelun Pharmaceutical, is the general partner of each of our Employee Incentive Platforms. As such, Kelun Pharmaceutical was entitled to exercise the voting rights attaching to the Shares held by our Employee Incentive Platforms. Therefore, as of the Latest Practicable Date, Kelun Pharmaceutical was able to exercise approximately 75.27% of the voting rights attaching to the Shares of our Company. Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Kelun Pharmaceutical will be entitled to exercise approximately [REDACTED]% voting rights attaching to the Shares directly held by it and those held by our Employee Incentive Platforms. Accordingly, Kelun Pharmaceutical and the Employee Incentive Platforms will continue to be a group of Controlling Shareholders of our Company upon the completion of the [REDACTED]. Pursuant to the Rules Governing the Listing of Shares on the Shenzhen Stock Exchange (《深圳證券交易所股票上市規則》) where Kelun Pharmaceutical is listed, an “actual controller” refers to an individual or entity that can control a company by way of investment relationship, contracts or other arrangements. Mr. LIU Gexin held approximately 25.77% equity interest in Kelun Pharmaceutical as of March 31, 2023 and is deemed as the actual controller of Kelun Pharmaceutical. Therefore, Mr. LIU Gexin is able to control Kelun Pharmaceutical and exert substantial influence over it. Considering Kelun Pharmaceutical itself is able to exercise more than 30% voting power at general meetings of our Company, Mr. LIU Gexin is entitled to, through Kelun Pharmaceutical, indirectly control the exercise of more than 30% of the voting power at general meetings of our Company. As such, we also regard Mr. LIU Gexin as our Controlling Shareholder. Therefore, Kelun Pharmaceutical, the Employee Incentive Platforms and Mr. LIU Gexin are considered as a group of Controlling Shareholders of our Company.

There is a clear business delineation of business between our Group and the Remaining Kelun Group. The Remaining Kelun Group is an integrated research-driven and market-oriented pharmaceutical company primarily focusing on: (i) manufacturing of IV (intravenous) fluids solution products and antibiotics intermediates; and (ii) research and development of generic drugs. In contrast, the overall business of our Group is at the pre-commercialization stage with R&D, manufacturing and commercialization of novel drugs to address medical needs. For details, see “Relationship with Our Controlling Shareholders” in this document.

CONNECTED TRANSACTIONS

Prior to the [REDACTED], our Group has entered into certain transactions in our ordinary and usual course of business with parties who will, upon the [REDACTED], become connected persons of our Company. We will continue to engage in certain connected transactions after the [REDACTED]. For details of such one-off connected transactions and continuing connected transactions of our Company following the [REDACTED], see “Connected Transactions.”

SUMMARY

We have applied for, and the Stock Exchange [has granted] us, waivers from strict compliance with (i) the announcement, circular and independent Shareholders’ approval requirements under Rule 14A.105 of the Listing Rules; and (ii) the requirement of setting a monetary annual cap set out in Rule 14A.53 of the Listing Rules. For details, see “Connected Transactions.”

PRE-[REDACTED] INVESTORS

Since the establishment of our Company, we have received several rounds of equity financing from our Pre-[REDACTED] Investors. Our diverse base of Pre-[REDACTED] Investors consists Sophisticated Investors such as IDG Capital and SDIC, which held approximately 4.80% and 3.69%, respectively, of the total issued share capital of our Company as of the Latest Practicable Date. Pursuant to applicable PRC laws, the Pre-[REDACTED] Investors shall not dispose of any of the Shares held by them within 12 months following the [REDACTED]. For details of our Pre-[REDACTED] Investments, see “History and Corporate Structure – Pre-[REDACTED] Investments” in this document.

DIVIDENDS

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future [REDACTED] for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our Board of Directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our products as well as our [REDACTED], capital requirements, overall financial condition and contractual restrictions. As confirmed by our PRC Legal Advisor, any future profit that we make will have to be applied to make up for our historically accumulated losses in accordance with the PRC laws, after which we will be obliged to allocate 10% of our profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient profit to our statutory common reserve fund as described above. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future.

[REDACTED] STATISTICS⁽¹⁾

	Based on an [REDACTED] of HK\$[REDACTED]	Based on an [REDACTED] of HK\$[REDACTED]
[REDACTED] of our Shares ⁽²⁾	HK\$[[REDACTED] million]	HK\$[[REDACTED] million]
Unaudited [REDACTED] adjusted net tangible liabilities of the Group per Share ⁽³⁾⁽⁴⁾	HK\$[REDACTED]	HK\$[REDACTED]

SUMMARY

Notes:

- (1) All statistics in this table are on the assumption that the [REDACTED] are not exercised.
- (2) The calculation of [REDACTED] is based on [REDACTED] Shares (including the issuance of 51,255,685 Shares pursuant to a share subscription and debt-to-equity swap agreement in January 2023 and the issuance of 26,076,205 Series B Shares with certain preferential rights issued to investors in February 2023) expected to be in [REDACTED] immediately after completion of the [REDACTED].
- (3) The [REDACTED] adjusted net tangible liabilities of our Group per Share is arrived at after making the adjustments referred to in “Appendix II – Unaudited [REDACTED] Financial Information” and on the basis that [REDACTED] shares (being the outstanding 116,050,609 Shares as of December 31, 2022 and [REDACTED] H Shares to be [REDACTED] pursuant to the [REDACTED], but excluding the issuance of 51,255,685 Shares pursuant to a share subscription and debt-to-equity swap agreement in January 2023 and the issuance of 26,076,205 Series B Shares with certain preferential rights issued to investors in February 2023) were in [REDACTED] immediately following the completion of the [REDACTED] assuming the [REDACTED] had completed on December 31, 2022 without taking into account of any Shares which may be issued upon the exercise of the [REDACTED].
- (4) No adjustment has been made to reflect our any trading results or other transactions entered into subsequent to December 31, 2022, including but not limited to the issuance of 51,255,685 Shares pursuant to a share subscription and debt-to-equity swap agreement in January 2023 and the issuance of 26,076,205 Series B Shares with certain preferential rights issued to investors in February 2023. Upon [REDACTED], these preferential rights of Series B Shares will be automatically cancelled and Series B Shares will be reclassified as equity. Had such Shares been issued and the [REDACTED] been completed on December 31, 2022, the unaudited [REDACTED] adjusted net tangible assets attributable to equity shareholders of the Company would have increased by approximately RMB[REDACTED] and the unaudited [REDACTED] adjusted net tangible assets per Share would have increased by approximately RMB[REDACTED] (equivalent to HK\$[REDACTED]).

[REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the indicative [REDACTED] range stated in this document. We currently intend to apply these [REDACTED] for the following purposes: (i) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our Core Products, namely, SKB264 and A166, including (a) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for clinical trial development and commercialization for SKB264, and (b) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for clinical trial development and commercialization A166, (ii) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our other key products, including A140, A167, A400 and A223, (iii) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the continued development of our technology platforms for ADCs, biologics and small molecules, advance our other existing pipeline assets, and explore and develop new drug candidates, (iv) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the expansion of our manufacturing capabilities and quality control system, and (v) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for working capital and other general corporate purposes. For further details, please see “Future Plans and [REDACTED].”

SUMMARY

[REDACTED]

[REDACTED] to be borne by us are estimated to be approximately HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share), representing approximately [REDACTED]% of the estimate [REDACTED] from the [REDACTED] assuming no [REDACTED] are [REDACTED] pursuant to the [REDACTED]. The [REDACTED] consist of (i) [REDACTED] expenses, including [REDACTED], of approximately HK\$[REDACTED] million, and (ii) [REDACTED] expenses of approximately HK\$[REDACTED] million, comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK\$[REDACTED] million, and (b) other fees and expenses of approximately HK\$[REDACTED] million. During the Track Record Period, the [REDACTED] charged to our consolidated statements of profit or loss were RMB[REDACTED] million (approximately HK\$[REDACTED] million) and the issue costs, which was recognized as prepayments and are expected to be deducted from equity upon the [REDACTED], were RMB[REDACTED] million (approximately HK\$[REDACTED] million). After the Track Record Period, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] million is expected to be accounted for as a deduction from equity upon the [REDACTED]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

Business Development

Since the end of the Track Record Period, we have continuously developed our business and continued to advance our pipeline. In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets for the treatment of cancer. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple preclinical ADC assets and exclusive options to obtain additional exclusive licenses to certain other preclinical ADC assets. We retain the right to research, develop, manufacture and commercialize certain of these ADCs for China, Hong Kong and Macau. For details, see “Business – Our License and Collaboration Arrangements – License and Collaboration Agreement with MSD for Up to Seven Preclinical ADC Assets.”

We received IND approvals from the FDA in November 2022 for a global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors, which we commenced in December 2022 in China. In January 2023, we received IND approval from the NMPA for SKB264’s phase 2 basket study as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC, and SKB264 was granted Breakthrough Therapy Designation for EGFR-TKI failed EGFR-mutant advanced NSCLC by the NMPA. We completed our Series B Financing in February 2023.

SUMMARY

As we strive to advance our pipeline and enhance our integrated drug development capabilities, we expect that we will continue to recognize net losses in 2023, primarily because we will continue to incur significant costs and expenses in relation to our R&D activities as we carry out and expand our preclinical and clinical development programs.

Regulatory Development

On February 17, 2023, the CSRC released the Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Trial Measures”), together with five interpretative guidelines thereof, which became effective on March 31, 2023 (the “Implementation Date”). The Trial Measures stipulated that domestic companies that seek to issue securities overseas, both directly and indirectly, shall complete the filing procedures and report relevant information to the CSRC. On the same date, the CSRC also released the Notice on the Arrangements for the Filing Management of Overseas Listing of Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》) (the “Notice”), which stipulated that prior to the Implementation Date, the CSRC would carry on its works on a normal basis pursuant to relevant regulations for the accepted applications for administrative approval for the overseas securities [REDACTED], under which circumstance if such companies could not obtain administrative approval prior to the Implementation Date, these companies shall complete the filing procedures with the CSRC.

As of the Latest Practicable Date, our Company had submitted overseas [REDACTED] application to the CSRC and obtained the letter of acceptance from the CSRC on February 17, 2023. The CSRC issued an approval letter on March 30, 2023 for the [REDACTED], the Conversion of Domestic Shares and Unlisted Foreign Shares into H Shares, and the application to [REDACTED] our H Shares on the Hong Kong Stock Exchange. Such approval is valid for 12 months. In granting such approval, the CSRC accepts no responsibility for the financial soundness of us or for the accuracy of any of the statements made or opinions expressed in this document. As advised by our PRC Legal Advisor, according to Trial Measures and the Notice, if the [REDACTED] is not completed within the validity period of the approval of the CSRC, we will be required to complete the necessary filing procedures for the [REDACTED] and the [REDACTED]. No other approvals under the PRC laws and regulations are required to be obtained for the [REDACTED] of the H Shares on the Stock Exchange.

Impact of the COVID-19 Pandemic

As of the Latest Practicable Date, we had not experienced material disruptions in our operations as a result of the COVID-19 pandemic. Although we encountered temporary slow-down in subject enrollment for certain clinical trials in China, the overall impact of the COVID-19 pandemic on our clinical activities, drug development timeline, business and results of operations has been immaterial, and especially as the COVID-19 pandemic has come under control as of the Latest Practicable Date.

SUMMARY

No Material Adverse Change

After performing due diligence work which our Directors consider appropriate and sufficient and after due and careful consideration, our Directors confirm that, except as disclosed above and up to the date of this document, there has been no material adverse change in our financial or trading position or prospects since December 31, 2022, which is the end date of the periods reported on in the Accountants' Report included in Appendix I to this document, and there is no event since December 31, 2022 that would materially affect the information as set out in the Accountants' Report included in Appendix I to this document.