
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 the entire Document 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 on the basis that we are unable to 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 such as ours. In addition, we have incurred significant operating losses since our inception, and we expect to remain loss making in the near term. We had negative net cash flow from operating activities during the Track Record Period. We did not declare or pay any dividends during the Track Record Period and do not intend to pay any dividends in the near future. Your [REDACTED] decision should be made in light of these considerations.

OVERVIEW

























Founded in 2019, we are an R&D-driven, dermatology-focused biopharmaceutical company focused on the broader dermatology treatment and care therapeutic areas, including localized adipose accumulation management medication, scalp diseases and care, skin diseases and care and topical anesthesia. We have one Core Product and eight other pipeline product candidates. We also distributed two commercialized products developed by overseas collaboration partners. Our Core Product, CU-20401, is a recombinant mutant collagenase that targets adipose accumulation as a manifestation of metabolic diseases such as obesity and overweight. As of the Latest Practicable Date, we held one patent in relation to our Core Product.


WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT.

Our Pipeline

The following chart summarizes the development stage of our major marketed products and product candidates, as well as distributed products of the Latest Practicable Date.

SUMMARY

Therapeutic Areas	Candidate ^e	Active Ingredients & Formulation	Indication	OTC / Prescription Drugs	Commercial Rights	Source	Pre-Clinical	IND	Phase I	Phase II	Phase III	Registration	Commercialization	Upcoming Milestone	Expected Commercial Launch	NMPA Registration Classification ¹⁰
Localized Adipose Accumulation Management	CU-20401 ¹ ★	Recombinant mutant collagenase	Submental Adipose Accumulation (Submental Fat)	Prescription drug	Asia	Acquired								Initiate Phase II in 3Q2023	2028	1
			Abdominal Adipose Accumulation (Abdominal Fat)	Prescription drug										Complete Phase I in 2024	2028	
Scalp Disease and Care	CU-40102 ² ■	Topical finasteride spray	Androgenic Alopecia	Prescription drug	Greater China ⁹	In-licensed								NDA submission to NMPA in 4Q2023	4Q2024	5.1
	CU-40101 ⁴	Topical small molecule thyroid hormone receptor agonist liniment		Prescription drug	Asia	In-licensed								Complete Phase I in 2Q2024	TBD	1
	CU-40103	Topical minoxidil foam	Alopecia	OTC	Global	Self-developed								ANDA submission to NMPA in 3Q2024	2025	3
	CU-40104	Topical dutasteride agent	Androgenic Alopecia	Prescription drug	Global	Self-developed								IND application submission to NMPA in 4Q2024	TBD	2
Skin Disease and Care	CU-10201 ⁵ ■	Topical 4% minocycline foam	Acne Vulgaris	Prescription drug	Greater China ⁹	In-licensed								NDA submission to NMPA in 4Q2023	4Q2024	5.1
	CU-10101 ⁶	Topical novel small molecule agent	Atopic Dermatitis	Prescription drug	Greater China ⁹ , Japan, South Korea and SEA	In-licensed								IND application submission to NMPA in 2Q2024	TBD	1
	CU-10401 ⁷	Topical tapinarof cream	Psoriasis	Prescription drug	Greater China ⁹ , Japan, South Korea and SEA	Acquired								ANDA submission to NMPA in 2026	2027	4
Topical Anesthesia	CU-30101 ⁸	Localized topical lidocaine and tetracaine cream	Surface Dermatologic Operations	Prescription drug	Greater China ⁹	Acquired								Commence Phase III in 2Q2023	2026	3

★ Denotes Core Product ■ Denotes Key Products  Denotes products in registrational trials in China with pilot commercialization in Lecheng, Hainan

SUMMARY

1. In addition to the product candidates listed below, we also entered into agreements for the distribution and marketing of CUP-MNDE and CUP-SFJH in Mainland China. CUP-MNDE has been commercialized by its original developer, Laboratoires Bailleul, and we entered into an agreement to obtain the exclusive rights for the distribution and marketing of CUP-MNDE in Mainland China while CUP-SFJH has been commercialized by its original developer, VML, and we entered into an agreement to obtain the exclusive rights for the distribution and marketing of CUP-SFJH in Mainland China.
2. We acquired from Rejuven Dermaceutical Co., Ltd., an Independent Third Party, in August 2020 all of the intellectual property and development results related to CU-20401 in Asia. For more details, see “Business – Collaboration and Licensing Arrangements – CU-20401 Agreement”. We have completed Phase I clinical trial for CU-20401 for subcutaneous adipose accumulation and expect to initiate a Phase II clinical trial of CU-20401 for subcutaneous adipose accumulation in the third quarter of 2023.
3. We in-licensed from Polichem S.A., a subsidiary of Almirall, S.A. (BME: ALM), an Independent Third Party, in November 2020 an exclusive, royalty-bearing, non-assignable and non-sublicensable license to develop, use, have used, distribute, market, promote, sell, have sold, offer for sale, import, label, package and otherwise commercialize CU-40102 in any uses in androgenic alopecia in Greater China. For more details, see “Business – Collaboration and Licensing Arrangements – CU-40102 Agreement”. CU-40102 is currently in a registrational Phase III clinical trial in China and has commenced pilot commercialization in Lecheng, Hainan.
4. We in-licensed from TechnoDerma Medicines Inc., an Independent Third Party, in May 2020 an exclusive, royalty-bearing, and assignable license to develop, manufacture and commercialize CU-40101 in Asia for dermatology indication of hair growth. For more details, see “Business – Collaboration and Licensing Arrangements – CU-40101 Agreement”.
5. We in-licensed from Foamix, an Independent Third Party, in April 2020 an exclusive, royalty-bearing license, under the patents, know-how and trademarks, with the right to sublicense to develop, use, have used, distribute, market, promote, sell, have sold, offer for sale, import, label, package and otherwise commercialize CU-10201 in any uses in moderate to severe acne vulgaris in Greater China. For more details, see “Business – Collaboration and Licensing Arrangements – CU-10201 Agreement”. The Phase III bridging clinical trial of CU-10201 for moderate-to-severe acne vulgaris sponsored by us was initiated in September 2021. We are collecting clinical data and expecting to complete the primary endpoint read-out for the Phase III bridging clinical trial in the first quarter of 2023.
6. We in-licensed from Wuhan Yingnashi Pharmaceutical Co., Ltd., an Independent Third Party, in November 2019 the exclusive rights in relation to CU-10101 in Greater China, Japan, South Korea and SEA.
7. We acquired from Wuhan Yingnashi Pharmaceutical Co., Ltd., an Independent Third Party, in June 2020 all development results and intellectual property rights in relation to CU-10401 in Greater China, Japan, South Korea and SEA.
8. We acquired from Sparkmed Research, LLC, an Independent Third Party, in November 2019 all the intellectual property and ownership of CU-30101 in Greater China. For more details, see “Business – Topical Anesthesia”.
9. Including Mainland China, Hong Kong, the Macau Special Administrative Region and Taiwan.
10. As advised by the PRC Legal Advisers, for the product candidates that have not obtained IND approval, the NMPA Registration Classification is subject to the confirmation by the NMPA.

SUMMARY

Localized Adipose Accumulation Management Medication

- *Core Product CU-20401.* CU-20401 is an acquired recombinant mutant collagenase that targets adipose accumulation as a manifestation of metabolic diseases such as obesity and overweight. We acquired CU-20401 from Rejuven Dermaceutical Co., Ltd. in August 2020. CU-20401 is being reviewed and will potentially be approved by the NMPA as a drug to be administered by registered healthcare practitioners. The route of administration of CU-20401 is subcutaneous injection. Fat cells are normally attached to the extracellular matrix composed of collagen network. CU-20401 acts as a collagenase that degrades extracellular matrix collagen in the subcutaneous fat layer, leading to apoptosis of adipocytes. CU-20401 is a recombinant collagenase II with the E451D mutation. The recombinant with the E451D mutation does not affect enzyme-substrate binding, but decreases enzymatic cleavage rate in vivo. CU-20401 is modified with reduced rate to catalyze the collagen degradation and is effective to reduce adipose accumulation with mild catalytic activity, thus reducing the adverse effects of wild-type collagenase, such as bruising and pain. The modification of E451D mutation for CU-20401 was carried out before our acquisition of CU-20401. The formulation of CU-20401 includes recombinant mutant collagenase, tromethamine, sucrose, calcium chloride, dihydrate hydrochloric acid and water. We have completed Phase I clinical trial on human subjects for CU-20401 for submental adipose accumulation (submental fat) and are conducting another Phase I clinical trial for abdominal adipose accumulation (abdominal fat). The significance of Phase I clinical trial is that its results suggested that CU-20401 is safe and well tolerated in subjects with submental adipose accumulation (submental fat). As we completed the Phase I clinical trial with no objection of entering a Phase II clinical trial, based on the NMPA’s IND approval, we expect to initiate a Phase II clinical trial of CU-20401 for submental adipose accumulation (submental fat) in the third quarter of 2023 to evaluate its efficacy profiles.

Scalp Diseases and Care

- *Key Product CU-40102.* CU-40102 is an in-licensed product and the first and only topical finasteride product approved for androgenetic alopecia treatment globally and the only topical finasteride under clinical development in China. We in-licensed CU-40102 from Polichem S.A. in November 2020. Finasteride can treat androgenetic alopecia in male patients by acting as a competitive and specific inhibitor of Type II 5-alpha reductase to inhibit the conversion of testosterone to DHT in the scalp.

SUMMARY

- *CU-40101*. CU-40101 is an in-licensed topical liniment to treat androgenetic alopecia. We in-licensed CU-40101 from TechnoDerma Medicines Inc. in May 2020. It contains a potent small molecule hormone receptor agonist that binds to thyroid receptor in hair follicle cells and induces hair growth. CU-40101 is to be applied to the scalp directly, reducing systemic exposure to the drug and the associated adverse effects.
- *CU-40103*. CU-40103 is a self-developed topical minoxidil foam for the treatment of alopecia. The active ingredient, minoxidil, is widely used and proven efficacious in clinical practice for both male and female hair regrowth.
- *CU-40104*. CU-40104 is a self-developed topical dutasteride to treat androgenetic alopecia. CU-40104’s topical formulation is being developed for direct dutasteride application to the site of action on the scalp. The topical formulation is expected to reduce systemic exposure and side effects as compared with oral dutasteride.

Skin Diseases and Care

- *Key Product CU-10201*. CU-10201 is an in-licensed product and the first and only topical minocycline approved for acne vulgaris treatment globally and the only topical minocycline under clinical development in China. We in-licensed CU-10201 from Foamix Pharmaceuticals Ltd. in April 2020. FDA approved CU-10201 for the treatment of moderate to severe acne vulgaris in the United States in 2019 under the brand name Amzeeq™ with Foamix Pharmaceuticals Inc. as the marketing authorization holder.
- *CU-10101*. CU-10101 is an in-licensed non-hormonal, small molecule drug targeting atopic dermatitis. We in-licensed CU-10101 from Wuhan Yingnashi Pharmaceutical Co., Ltd. in November 2019.
- *CU-10401*. CU-10401, an acquired aryl hydrocarbon receptor (AhR) targeted non-steroidal small molecule chemical drug in topical form, is a generic tapinarof cream targeting psoriasis currently being developed in pre-clinical stage. We acquired CU-10401 from Wuhan Yingnashi Pharmaceutical Co., Ltd. in June 2020. The active ingredient of CU-10401, tapinarof, is reported to bind and activate AhR, decrease pro-inflammatory cytokines, and regulate skin barrier protein expression to promote skin barrier normalization.

Topical Anesthesia

- *CU-30101*. CU-30101 is an acquired localized lidocaine and tetracaine compound topical anesthesia cream. We acquired CU-30101 from Sparkmed Research, LLC. in November 2019.

SUMMARY

Distributed Products

- *CUP-MNDE*. CUP-MNDE is a commercialized, over-the-counter minoxidil spray indicated for alopecia developed by Laboratoires Bailleul International S.A. We have exclusive distribution rights to develop the distribution and marketing of CUP-MNDE in Mainland China. Laboratoires Bailleul International S.A. is the market authorization holder. We commenced distribution with the brand name Bailleul® in January 2022 in Mainland China excluding Hong Kong, Macao and Taiwan.
- *CUP-SFJH*. CUP-SFJH, as a cosmetic product, is a commercialized hair growth serum featuring a non-hormonal formula of natural plant extracts developed by Van Montfort Laboratories B.V. We have exclusive distribution rights to develop the distribution and marketing of CUP-SFJH in Mainland China. Van Montfort Laboratories B.V. is the market authorization holder of CUP-SFJH. We commenced commercialization with the brand name ESTHECIN® in August 2022 in Mainland China excluding Hong Kong, Macao and Taiwan.

ADDRESSABLE MARKETS AND COMPETITIVE LANDSCAPE OF CORE PRODUCT

CU-20401 is developed as a localized adipose accumulation management medication for dermatology treatment. China’s localized adipose accumulation management medication market is still at an early stage of growth with no approved products. However, according to Frost & Sullivan, the market size of localized adipose accumulation management medication is estimated to grow because (i) a number of localized adipose accumulation medications are expected to be approved in China, (ii) the recognition and availability of localized adipose accumulation medications continue to improve due to their increased safety profiles and ease of treatment, (iii) China’s obese and overweight population that can receive adipose accumulation management medication is estimated to continue to grow, (iv) patients receiving adipose accumulation management medication generally demonstrate a high re-purchase rate in order to maintain the desired results, (v) the education and promotion of physicians by each product manufacturer continues to increase the clinical penetration of the products, (vi) the clinical use of the products in hospitals will increase the credibility of the products and the number of users. For details, see “Industry Overview” section in this Document. The market size of localized adipose accumulation management medications for labelled use is expected to grow from RMB86.7 million in 2023 to RMB514.4 million in 2025, representing a CAGR of 143.6% from 2023 to 2025. The market in 2030 is expected to reach RMB2,439.9 million, representing a CAGR of 36.5% from 2025 to 2030. According to Frost & Sullivan, the number of female and male targeted patients with adipose accumulation in China in 2021 is 170.1 million and 181.9 million, respectively, and is expected to reach 210.7 million and 223.6 million, respectively, in 2030. The addressable market of the Core Product only constitutes a very small subset of the entire broader dermatology treatment and care market in China.

SUMMARY

An individual has three statuses with respect to body weight from normal weight to obesity, namely normal weight, overweight and obesity. Overweight and obesity are defined as abnormal or excessive fat accumulation that increases the risk of noncommunicable diseases, including (i) cardiovascular diseases, which are mainly heart disease and stroke, the leading cause of death in recent years; (ii) diabetes; (iii) musculoskeletal disorders, especially osteoarthritis, a highly disabling degenerative disease of the joints; and (iv) some cancers, including endometrial, breast, ovarian, prostate, liver, gallbladder, kidney, and colon cancers. In China, normal weight is defined as a body mass index between 18.5 kg/m^2 and 23.9 kg/m^2 , overweight is a body mass index of more than or equal to 24 kg/m^2 , and obesity is a body mass index of more than or equal to 28 kg/m^2 in adults. As a potential Class I New Drug to be approved by the NMPA, CU-20401 targets adipose accumulation as a manifestation of metabolic diseases such as obesity and overweight. The trial sponsor is required to conduct Phase I, II and registrational clinical studies on CU-20401, with multiple dosing and follow-up visits during the study or treatment cycle. As advised by our PRC Legal Advisor, CU-20401 is regulated by the Regulations for the Implementation of the Drug Administration Law of the PRC. After its launch, we plan to implement an academic-oriented promotion and commercialization strategy. Our medical institution network is expected to cover 20 Class III Grade A hospitals in more than 10 cities in Eastern and Northern China in the first two years after its market launch. Since CU-20401 is a prescription-only medication, it is, under the Order of the State Drug Administration on Promulgating the Measures for the Classified Administration of Prescription Drugs and Over-the-Counter Drugs, required to be prescribed by a licensed Practicing Physician or Assistant Practicing Physician at a medical institution with the Medical Practice License.

We commenced and completed the Phase I clinical trial on human subjects for CU-20401 for submental adipose accumulation (submental fat) in February 2022 and November 2022, respectively. We commenced the Phase I clinical trial on human subjects for CU-20401 for abdominal adipose accumulation (abdominal fat) in December 2021.

According to Frost & Sullivan, currently there is no standard of care to manage localized adipose accumulation as recommended under national and international guidelines, and that in China, no adipose tissue management product has been certified as a drug to date. In China, there are a few adipose tissue management products approved by the NMPA, but those are cosmetic products that are approved for topical application only and are not indicated for adipose accumulation management administration into the human body. Most currently available products are composed of natural extract and peptides, which can only temporarily shrink fat cells, but there is insufficient evidence to suggest they permanently decompose fat cells to achieve long-term efficacy and desired outcomes. For details, see “Industry Overview” section in this Document.

SUMMARY

The table below sets forth the competitive landscape of our Core Product CU-20401 in China. Three product candidates are in clinical trial stages in China. Deoxycholic acid, which has the most advanced clinical program to date, may have first-mover advantage in the market. CU-20401 is not proposed or intended to be the sole option for addressing obesity, overweight and metabolic diseases. It also may be challenging for us to obtain approval for the use of CU-20401 for abdominal adipose accumulation as no similar drugs have been approved for the same indication.

Drug	Registration Classification ⁽¹⁾	Applicant	Indication	Stage	First Posted Date ⁽²⁾
Deoxycholic Acid	3	Nanjing Noratech	Improvement in moderate to severe contour bulging/excessive facial fullness due to the accumulation of submental fat in adults	Phase III	2021/09
CU-20401	1	Cutia	Improvement in submental adipose accumulation in adults	Phase I completed	2021/08
			Improvement in abdominal adipose accumulation in adults	Phase I (ongoing)	
Deoxycholic Acid	3	Nanjing Minova	Submental fat	IND Approval	2021/07

Notes:

1. Registration Classification:

Class 3: Drugs manufactured by domestic applicants by imitating the original drugs that have been marketed overseas but not yet in China

Class 1: Innovative drugs that have not been marketed in China or overseas

- First posted date denotes the date when the trial is first publicly announced on the CDE website. Information as of November 4, 2022. Phase I trial of CU-20401 in submental adipose accumulation has been completed.
- Deoxycholic acid (Kybella) is an approved localized adipose accumulation management medication globally indicated for improvement in the appearance of moderate to severe convexity or fullness associate with submental fat in adults. A Phase II clinical trial of Sisram Medical Ltd. (Sisram)’s product candidate RZL-012 has been completed in the U.S. Sisram planned to commence a Phase III clinical trial in China, and such trial has not commenced as of the Latest Practicable Date.
- According to Frost & Sullivan, in the Phase III trials of Kybella, adults with a moderate or severe amount of SMF (as graded by both the clinician using CR-SMFRS and the patient using PR-SMFRS) who were dissatisfied with the appearance of their face/chin based on rating of the SSRS were randomized 1:1 to either Kybella or placebo for up to 6 treatment sessions (every 28 ± 5 days), and efficacy assessments were conducted at 12 weeks after last treatment.

The primary endpoints were percentage of patients who achieved a ≥1-grade improvement in SMF from baseline based on both clinician (CR-SMFRS) and patient (PR-SMFRS) assessment (composite CR-1/PR-1 response), and percentage of patients who achieved a ≥2-grade improvement in SMF from baseline (composite CR-2/PR-2 response). Secondary endpoints included the percentage of patients who achieved a ≥10% reduction from baseline in submental volume based on MRI and mean change from baseline in the psychological impact of SMF using PR-SMFIS.

Safety was assessed throughout the trials via spontaneous reports of adverse events and findings from clinical laboratory tests, vital sign assessments, and physical examinations.

Source: CDE, Frost & Sullivan analysis

SUMMARY

We position CU-20401 as a potential Class I New Drug to be approved by the NMPA indicated for adipose accumulation as a manifestation of metabolic diseases such as obesity and overweight rather than for aesthetic purposes, which would be prone to off-label uses.

The NMPA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to liability. According to Drug Administration Law, off-label uses of drugs will be identified as a counterfeit drug. Whoever produces or sells any counterfeit drug shall be ordered to suspend production and business for rectification and its illegal proceeds derived therefrom confiscated and its relevant drug approval certificate revoked, and concurrently be imposed a fine of not less than 15 times but not more than 30 times the value of the drug illegally produced and sold. If the circumstances are deemed to be serious by the NMPA, the company’s drug production license, drug business license or pharmaceutical preparation license for medical institutions shall be revoked, for which no application by it will be accepted for ten years. In addition to adhering to the national regulation, we aim to adopt the following measures to prevent off-label use of CU-20401: (i) provide one-month trainings to educate physicians before administration of CU-20401, and provide notice that CU-20401 is indicated for adipose accumulation, and accordingly shall only be prescribed for such indications, and that physicians should prescribe medications only for NMPA-approved indications and avoid off-label uses to ensure compliance with relevant legal requirement; (ii) maintain close communication with KOLs and clinical experts with the aim to ensure the proper administration and prescription of CU-20401, and implement a reporting mechanism and form a dedicated market inspection team to coordinate with medical institutions to ensure prescription compliance with relevant legal requirements. We may suspend product supply or terminate the relevant distribution arrangements pursuant to the relevant contracts, if the medical institution fails to comply with the legal prescription requirements and rectify within the prescribed time.

Despite the measures to be taken above, there remains the risk that our CU-20401, upon regulatory approval, is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by relevant authorities. This occurrence may render our CU-20401, upon regulatory approval, less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including our share price upon [REDACTED]. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates. For details, see “Risk Factors” in this Document.

SUMMARY

OUR STRENGTHS

We believe the following strengths differentiate us from our competitors:

- Well-positioned in the broader dermatology treatment and care industry to capture market potential
- Integrated capabilities covering the entire broader dermatology treatment and care industry value chain
- Continuous innovation driven by our customer-centric philosophy, proprietary CATAME[®] technology platform
- Comprehensive pipeline captures large market potential and unmet needs
- Experienced Management Team

OUR STRATEGIES

We plan to pursue the following significant opportunities and execute our key strategies accordingly:

- Focus on customer needs and utilize integrated industrial capabilities to provide alternative dermatology management solutions
- Continue to advance the clinical development of our product portfolio
- Expand our ecosystem coverage and build our commercialization team
- Expand our presence

RESEARCH AND DEVELOPMENT

We have developed our clinical and pre-clinical pipeline through a combination of self-development and licensing arrangements. Leveraging our R&D experience in the broader dermatology treatment and care fields, including scalp diseases and care, skin diseases and care, localized adipose accumulation management medication and topical anesthesia, we have developed our proprietary CATAME[®] technology platform, which will continue to drive the development and innovations of distinct products.

- Our CATAME[®] technology platform is an integrated R&D platform with high entry barriers. Our CATAME[®] technology platform, which includes Colloidal-Emulsification-Active Encapsulation (CEAE) platform, Aerosol (ARS) platform, Transdermal Delivery (TDD) platform, Actives & Formulation Evaluation (AFE) platform, Micro/Nano-Particulates & Self-Assembly (MiSA) platform and Ex vivo

SUMMARY

& Efficacy Evaluation (EVEE) platform, is one of the only few platforms in China that facilitate development of products covering a variety types of dermatological diseases. Our CATAME[®] technology platform integrates capabilities to customize transdermal delivery characteristics of drugs, develop micron and nano-sized particulates, evaluate formulation quality and stability and perform cutaneous pharmacokinetic analysis during the development process. The CATAME[®] technology platform enables the development of a wide range of product dosage forms and the relevant formulation technology. Through the platform, we have built a competitive product pipeline of creams, sprays, ointments, aerosol foams and other dosage forms.

- Leveraging on the CATAME[®] technology platform, we could provide customers a product pipeline consisting of multiple candidates in various dosage forms. Our platform also helps design the most suitable product formats that are key to specific and successful drug delivery.
- During the drug discovery stage, our R&D team explores new chemical entities, structure-activity-relationship analysis based on a thorough biological understanding of the disease. Our R&D team also coordinates and accomplishes pre-clinical R&D activities on the product candidates’ pharmacology, pharmacokinetics and toxicology during the drug evaluation stage. Our drug discovery capabilities comprise (i) a targeted screening and validation approach that screens, validates and develops specific biological targets based on unmet medical needs; (ii) multi-functional technology platforms including synthetic chemistry, analytical chemistry, biology, formulation, and toxicology; and (iii) supporting systems including intellectual properties and quality assurance.

As of the Latest Practicable Date, our R&D team consisted of approximately 32 employees. Among our R&D team members, 11 members have obtained master degrees, and seven members held doctorate degrees. Our experienced in-house R&D team comes from a variety of medical backgrounds and have diverse and in-depth knowledge that is critical to strengthening our R&D capabilities in dermatology, topical and transdermal drug formulation and delivery, and synthesis of novel molecules and assemblies. Our medical team covers clinical operations, clinical quality control, pharmacovigilance, and designing, planning and management of multiple clinical trials across China. Our integrated team spans market intelligence, drug discovery, clinical development, business development and regulatory affairs. We benefit from their deep insights into the sciences and the market in developing products that strive to meet our customers’ unmet needs. In 2021 and 2022, we recorded R&D costs of RMB110.6 million and RMB180.8 million, respectively. In 2021 and 2022, we recorded R&D costs of RMB19.7 million and RMB23.8 million, respectively, for our Core Product CU-20401.

SUMMARY

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we held 18 patents and patent applications (including in-licensed patents and patent applications) in Mainland China, Hong Kong and Japan. The following table sets forth an overview of our material granted patent for our Core Product as of the Latest Practicable Date:

Product Candidate	Name of Patent	Jurisdiction	Status	Patent Expiration ⁽¹⁾	Market Commercial Rights of the Company
CU-20401	A recombinant variant collagenase preparation method and its application	Mainland China	Granted ⁽²⁾	2038-07-30	Exclusive

Notes:

- (1) The patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
- (2) The patent was invented by employees of Rejuven. The patent application was filed by Rejuven on July 30, 2018 in Mainland China and issued on May 12, 2020 to Rejuven. Pursuant to the CU-20401 Agreement, Rejuven transferred the patent ownership to us in October 2020. We are the current owner of the patent in Mainland China. After our patent acquisition of CU-20401, Rejuven does not hold any patents in relation to CU-20401 in Asia. We do not have plans to file patent applications for CU-20401 in countries other than China.

We conduct our business under the brand name “Cutia”. As of the Latest Practicable Date, we had 102 registered trademarks and filed 63 trademark applications in Mainland China and Hong Kong. We are also the registered owner of one domain name.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent. To our best knowledge, we are not aware of any potential or material claims or disputes in relation to the infringement of intellectual properties of our products during the Track Record Period.

SUMMARY

COLLABORATION AND LICENSING ARRANGEMENTS

CU-20401 Agreement

On August 28, 2020, we entered into an agreement (the “**CU-20401 Agreement**”) with Rejuven Dermaceutical Co., Ltd., (“**Rejuven**”), an Independent Third Party and a PRC company specializing in the R&D of pharmaceutical products in China.

The CU-20401 Agreement specified two parts, namely asset transfer and joint collaboration.

Asset Transfer

Pursuant to the CU-20401 Agreement, Rejuven has exclusively transferred to us all of the intellectual property and development results related to CU-20401 in Asia (“**Asset Transfer**”).

As confirmed by Rejuven, Rejuven was the sole and exclusive owner of the intellectual property rights of CU-20401 worldwide before the Asset Transfer. After the Asset Transfer, we are the sole and exclusive owner of the intellectual property rights of CU-20401 in Asia and Rejuven is the sole and exclusive owner of the intellectual property rights of CU-20401 in areas outside Asia. We are the market authorization holder of CU-20401 in all markets within Asia. Before, during and after the launch of CU-20401, we have exclusive rights to develop, manufacture and commercialize CU-20401 in Asia for all existing and future potential indications, including but not limited to adipose accumulation management and other indications such as cellulite repair and scar modification. To our best knowledge, we are the sole and exclusive company to have acquired the intellectual property rights of CU-20401 in Asia and based on the confirmation of Rejuven, such intellectual property rights had not been granted by Rejuven to other parties before the Asset Transfer.

As of the Latest Practicable Date, all such intellectual property and information, including know-how, had been transferred to us. We will be the sole owner of any improvements to the transferred patents and data and IP rights that are discovered, generated, developed, invented or created by us in Asia. We will develop and commercialize CU-20401 at our own costs and expenses in Asia, and we are entitled to the ownership and rights with respect to our R&D work of CU-20401 within Asia.

For the Asset Transfer, we are required to pay an aggregate of RMB20.0 million in non-refundable upfront fees. As of December 31, 2022, we had paid RMB20.0 million as the non-refundable upfront fee.

The Asset Transfer has been irrevocably completed and settled, and nothing will invalidate, void or reverse our exclusive ownership of intellectual property rights for CU-20401 in Asia and will not affect our R&D, manufacturing and commercialization activities in Asia in all material aspects because after such Asset Transfer, we are the sole and exclusive owner of the intellectual property rights of CU-20401 in Asia. The patent transfer has also been recorded with the China National Intellectual Property Administration, and thus we are currently the registered patent owner of the patent for CU-20401 under China Patent Law.

SUMMARY

Joint Collaboration

Both parties formed a joint steering committee (“**Joint Steering Committee**”) and held the first meeting. The Joint Steering Committee consisted of two members appointed by each party to regularly discuss the development plan of CU-20401 for current and future expanded indication, and coordinate resources to ensure the effective advancement of the development (“**Joint Collaboration**”) plan for current and future indication expansion. We act as the principal party responsible for executing the clinical development plan formulated together with Rejuven and Rejuven is primarily responsible for advising on the development plan of CU-20401 in Asia. Rejuven will also provide assistance and support in our R&D, manufacturing and registration of CU-20401 in Asia. Rejuven can monitor its clinical progress in the U.S. based on our clinical progress and study results in Asia. We will discuss any adverse event in the clinical results. We do not make any representations and undertakings in the event of unfavorable clinical results. For matters that need to be decided in the development plan, the Joint Steering Committee shall discuss and give a resolution by a majority vote of the Joint Steering Committee members. Each member of the Joint Steering Committee shall have one vote, and if a resolution cannot be made or is disputed, our CEO shall have the final-decision marking authority.

In connection with the Joint Collaboration, we are required to pay Rejuven an aggregate of (i) RMB40.0 million of development milestones payments, and such development milestones include successful completion of first-patient-in in Asia and receipt of regulatory approval for marketing in Asia, (ii) an aggregate of RMB35.0 million of commercial milestones upon achievement of specific levels of aggregate annual net sales for CU-20401 in Asia, and (iii) tiered royalty payments calculated as a percentage of annual net sales of CU-20401 in Asia after its market launch, including (a) 4% of annual net sales of CU-20401 in Asia if the annual net sales are within a specific level, and (b) a further negotiated percentage if the annual net sales of CU-20401 in Asia is more than another specific level. We are not required to pay any tiered royalty payments before the launch of CU-20401 in Asia. As of December 31, 2022, we had paid RMB5.0 million as the first installment of development milestone payment upon first-patient-in of Phase I clinical trial in China.

Unless terminated earlier, the Joint Collaboration was effective on August 28, 2020 and will expire 20 years after the first commercial launch of CU-20401. After expiration, we are still entitled to continue all development, manufacturing commercialization activities related to CU-20401 in Asia.

The Joint Collaboration can be terminated on the following conditions: (i) a change in management or ownership of a counterparty that materially affects or impedes that party’s performance for the Joint Collaboration under the CU-20401 Agreement, which includes, a change in control that leads to (a) our failure to initiate an IND application with any competent authorities in Asia within two years of signing the agreement or failure to complete the first-patient-in in the Phase I clinical trial in Asia within three years; and (b) a delay of more than six months in the CU-20401 clinical progress compared to the development plan, and the breaching party fails to make restitution or cure within 60 days after receiving a written notice

SUMMARY

from the other party; (ii) insolvency events that a party loses the ability to pay its debts or files for bankruptcy and has appointed an administrator of the bankruptcy estate to administer all or a portion of its assets, or (iii) either party breaches the CU-20401 Agreement and the breaching party fails to make restitution or cure within 10 days after receiving a written notice from the other party or within a mutually agreed period of time.

In the event of expiry or termination of the CU-20401 Agreement, (i) only Asset Transfer will remain to be effective while Joint Collaboration will also to be ceased our obligation to pay milestone payment and tiered royalty payment for the Joint Collaboration will also cease. In the event of termination of the CU-20401 Agreement, (i) we should stop using, return or destroy all Rejuven’s documents, which Rejuven delivered to us, which includes patent documents, clinical trial documents and others that are not immaterial to our R&D of CU-20401 in Asia after Asset Transfer, (ii) we need to compensate for all direct losses caused to Rejuven if we fail to make development milestone payments twice or more than twice. If the clinical progress of CU-20401 is delayed for more than six months due to the breaching party’s failure to perform its contractual obligations, the breaching party shall compensate all direct losses and additional RMB1.0 million to the other party. In that case, Rejuven should compensate all our direct losses, including but not limited to our settled milestone and royalty payments.

We believe the likelihood that Rejuven will terminate the CU-20401 Agreement is low because (i) the mutual benefit for the Joint Collaboration, Rejuven is our close collaboration partner in Asia and we believe its interest is substantially aligned with us, which would be negatively affected by the termination of the Joint Collaboration; (ii) during the Track Record Period and up to the Latest Practicable Date, we communicated with Rejuven regarding our R&D activities performed and anticipated R&D plans for CU-20401, and we did not experience any conflicts or major issues with Rejuven and Rejuven had not raised any concerns on our clinical progress for the Joint Collaboration; (iii) we had not encountered any significant delays in the clinical progress of CU-20401, even during the COVID-19 pandemic in 2022. In case of termination of Joint Collaboration, we believe its impact on our R&D, manufacturing and commercialization of CU-20401 in Asia is immaterial as (i) we are the main responsible party for development and commercialization of CU-20401 to advance the project and Rejuven is to provide assistance and advice to our development plan during the Joint Collaboration, (ii) during the Track Record Period and as of the Latest Practicable Date, our R&D of CU-20401 in China did not substantially depend on Rejuven’s assistance.

CU-40102 Agreement

On November 2, 2020, we entered into a licensing agreement (the “**CU-40102 Agreement**”) with Polichem S.A. (“**Polichem**”), a subsidiary of Almirall, S.A. (BME: ALM) (“**Almirall**”), an Independent Third Party.

SUMMARY

Pursuant to the CU-40102 Agreement, Polichem granted to us an exclusive, royalty-bearing, non-assignable and non-sublicensable license to develop, use, have used, distribute, market, promote, sell, have sold, offer for sale, import, label, package and otherwise commercialize CU-40102 in any uses in androgenetic alopecia in Greater China consisting of Mainland China, Taiwan, Hong Kong and Macao.

In consideration of the licenses and rights granted to us, the down payments and the maximum milestone payments payable by us amount to €13.8 million in the aggregate, which includes €5.25 million non-refundable down payments and €8.5 million milestone payments consisting of commercial milestone payments. We are also obligated to pay tiered royalties of single digit percentage of annual net sales of CU-40102. As of the Latest Practicable Date, we had paid €4 million under the CU-40102 Agreement, which was part of the non-refundable down payments. We expect to pay the remaining non-refundable down payment upon the marketing authorization by NMPA and the successful first sales of CU-40102.

Unless otherwise terminated, the term for the CU-40102 Agreement is 15 years with automatic renewals.

CU-40101 Agreement

On April 17, 2020, we entered into a licensing agreement (the “**CU-40101 Agreement**”) with TechnoDerma Medicines Inc. (“**TechnoDerma**”), an Independent Third Party.

Pursuant to the CU-40101 Agreement, TechnoDerma grants to us an exclusive, royalty-bearing, and assignable license to develop, manufacture and commercialize CU-40101 in Asia for dermatology indication of hair growth (the “**CU-40101 Field**”). We will develop, obtain marketing authorization and commercialize CU-40101 at our own costs and expenses and conduct commercialized activities in the CU-40101 Field in Asia.

In consideration of the licenses and rights transferred to us, we are required to pay an aggregate of RMB60.0 million in non-refundable upfront fees of RMB15.0 million and development milestone payments of RMB45.0 million. We are also required to make payments when commercial milestones are met, which relate to the amount of aggregate net sales, such as tiered royalty payments calculated as a low single digit percentage of net sales of CU-40101 in Asia. As of the Latest Practicable Date, we had paid non-refundable upfront fees of RMB15.0 million and development milestone payments of RMB5.0 million under the CU-40101 Agreement.

The term for the CU-40101 Agreement is 20 years from launch of CU-40101. Unless terminated earlier, the CU-40101 Agreement will continue in full force and effect.

SUMMARY

CU-10201 Agreement

On April 21, 2020, we entered into a licensing agreement (the “**CU-10201 Agreement**”) with Foamix, an Independent Third Party. Pursuant to the CU-10201 Agreement, we are granted an exclusive, royalty-bearing license, under the patents, know-how and trademarks, with the right to sublicense to develop, use, have used, distribute, market, promote, sell, have sold, offer for sale, import, label, package and otherwise commercialize CU-10201 in any uses in moderate to severe acne vulgaris in Greater China including Mainland China, Taiwan, Hong Kong and Macao. Foamix later merged into VYNE Therapeutics Inc. in later 2021. VYNE Therapeutics Inc. had assigned rights and obligations of Foamix under CU-10201 Agreement to Journey Medical Corporation effective as of January 12, 2022.

In consideration of the licenses and rights granted to us, the non-refundable upfront payments and the maximum milestone payments payable by us amount to US\$11.0 million in the aggregate, which includes US\$10.0 million upfront payments and US\$1.0 million milestone payment within 30 business days after the first regulatory approval of the CU-10201 by the NMPA. We are also obligated to pay tiered royalties of single digit percentage of annual net sales of CU-10201. As of the Latest Practicable Date, we had paid US\$10.0 million under the CU-10201 Agreement.

Unless terminated earlier, the CU-10201 Agreement will continue in full force and effect the later of (i) ten years from the date of first commercial sales of CU-10201 in Greater China (ii) expiration of the last valid claim of patent covering CU-10201 in Greater China.

CUP-MNDE Agreement

On June 1, 2021, we entered into a distribution agreement (the “**CUP-MNDE Agreement**”) with Laboratoires Bailleul International S.A. (“**Laboratoires Bailleul**”), an Independent Third Party. Pursuant to the CUP-MNDE Agreement, Laboratoires Bailleul grants to us individual, direct and exclusive distribution rights to develop the distribution and marketing of the CUP-MNDE in Mainland China excluding Hong Kong, Macao and Taiwan. Laboratoires Bailleul also authorizes us to use the logos and commercial brands of CUP-MNDE in Mainland China. We shall obtain all necessary marketing authorization and/or registration of the products from the relevant authorities in Mainland China either alone, or with the assistance of Laboratoires Bailleul or a local Independent Third Party chosen by Laboratoires Bailleul. Unless terminated earlier, the CUP-MNDE Agreement has an initial term beginning on June 1, 2021, and ending on May 31, 2024 with automatic annual renewal thereafter unless it is terminated by written notice by either party at least three months before the expiration date.

SUMMARY

CUP-SFJH Agreement

On September 1, 2021, we entered into a distribution agreement (the “**CUP-SFJH Agreement**”) with Van Montfort Laboratories B.V. (“**VML**”), an Independent Third Party. Pursuant to the CUP-SFJH Agreement, VML grants to us the individual, direct and exclusive distribution rights within Mainland China excluding Hong Kong, Macao and Taiwan for CUP-SFJH. VML also authorizes us to use the logos and commercial brands of CUP-SFJH in the Mainland China during the term and in pursuit of the CUP-SFJH Agreement. The CUP-SFJH Agreement has an initial term beginning on September 1, 2021, and ending on December 31, 2024 with automatic renewal thereafter annually unless it is terminated by written notice at least three months before the expiration date.

CUSTOMERS

During the Track Record Period, apart from our five largest customers in each year who are our distributors, our customers are all individual customers. The total revenue generated from our five largest customers in each year amounted to RMB381,000 and RMB4,646,000 in 2021 and 2022, respectively. In 2021 and 2022, our five largest customers in each year together accounted for 18.7% and 40.9%, respectively, of our total revenues in the same years, and our largest customer accounted for 18.7% and 39.4%, respectively, of our total revenues in the same years. None of our five largest customers in each year is our supplier.

To the best of our knowledge, all of our five largest customers in each year during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates or any shareholder who, to the 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 during the Track Record Period.

SUPPLIERS

During the Track Record Period, we primarily procured raw materials and equipment to develop and manufacture our product candidates from reputable manufacturers and suppliers. Our purchases mainly include third-party contracting services (CRO and CDMO services) for pre-clinical evaluation and clinical trials of our product candidates and raw materials, and equipment. In 2021 and 2022, our purchases from our five largest suppliers in each year in the aggregate accounted for 59.4% and 43.6% of our total purchases (including value-added tax), respectively, and our purchases from the largest supplier accounted for 28.2% and 15.9% of our total purchases (including value-added tax), respectively.

To the best of our knowledge, all of our five largest suppliers in each year during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates or any shareholder who, to the 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 during the Track Record Period.

SUMMARY

OUR SALES, DISTRIBUTION AND MARKETING

We implement our marketing strategy primarily through online and offline channels. We have established a duo-channel distribution network to effectively reach our customers. Our distribution network includes direct sales and sales to distributors. As our reputation and capacity in developing and manufacturing high quality product candidates for broader dermatology treatment and care continues to grow, we plan to expand our sales network to mass market.

Product Pricing

We formulate, and implement, a reasonable pricing strategy for our marketed products to stay competitive and profitable. We take into account a number of factors in determining our prices, which primarily include our R&D, production and marketing costs and expenses, the perceived value of products, our market share and the competitive landscape.

Currently, none of our commercialized products have been included into the National Reimbursement Drug List (“**NRDL**”) or National Essential Drug List (“**NEDL**”). In order to gain market share against existing and future branded and generic competitors, we will also consider seeking inclusion of some of our products into the NRDL or NEDL and other reimbursement programs. As of now, our products are mainly in the clinical development or pilot commercialization stages, and since both NRDL and NEDL utilize a dynamic adjustment mechanism, they could potentially be eligible for either list and confirmation from the competent authority is required to verify their eligibility, as advised by our PRC Legal Advisor. As of the Latest Practicable Date, as advised by our PRC Legal Advisor, the inclusion in the NRDL of localized adipose accumulation medication for the treatment of obesity disease are not mandatory. As of the date of this document, we did not plan to seek inclusion of our Core Product into public reimbursement programs due to pricing considerations. We may seek alternatives such as commercial private insurance coverage of our products and expand our sales channels and explore new collaboration partnerships, such as engaging more distribution partners in China, to maximize the sales potential of our products and enhance our commercialization capability, especially on customer reach. Currently, we collaborate with reputed hospitals for clinical trials of CU-20401 in China. After its launch, we plan to implement an academic-oriented promotion and commercialization strategy pursuant to which we plan to market and sell CU-20401 to qualified medical institutions that hold the Medical Practice License.

As advised by our PRC Legal Advisor, the laws and regulations governing PRC pharmaceutical operation and internet pharmaceutical transaction services are not applicable to our dealing of CUP-MNDE and CUP-SFJH. Such laws and regulations are applicable to the activities of drugs production and transaction within the jurisdiction of the PRC, whereas we do not sell any drugs through our own websites or provide any third parties with internet drug trading services. Our distribution of products is generally conducted by Cutia HK, which is incorporated in Hong Kong and procures CUP-MNDE and CUP-SFJH for distribution. Cutia HK directly sells CUP-MNDE and CUP-SFJH to customers through the Tmall Global

SUMMARY

e-commerce platform and sells another portion of CUP-MNDE through a distributor in Hong Kong, which then sells our products to a sub-distributor, JD Health. Pursuant to the Customer Notice (消費者告知書/用戶須知) displayed on the websites of such third-party cross-border ecommerce platforms, purchases of products thereon are deemed to be overseas purchases, which is acknowledged by the customers. Our PRC Legal Advisor is of the view that the PRC laws and regulations governing pharmaceutical operations (including two-invoice system) and internet pharmaceutical transaction services are not applicable to our sales of CUP-MNDE and CUP-SFJH.

As advised by our PRC Legal Advisor, we are in compliance with all material applicable rules and regulations relevant to the two-invoice system in the PRC.

OUR CONTROLLING SHAREHOLDERS

Immediately after the completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no further Shares are issued under the [REDACTED] Equity Incentive Plan), the 6 Dimensions Entities will be in aggregate interested in approximately [REDACTED]% of the total issued share capital of our Company and will be our Controlling Shareholders as defined under the Listing Rules upon [REDACTED]. For more details, see “Relationship with our Controlling Shareholders” in this Document.

OUR [REDACTED] INVESTORS

The [REDACTED] Investments included Series A-1 and Series A-2 Financing, Series B Financing and Series C Financing. The total funds raised by the Company from the [REDACTED] Investments were approximately US\$275 million. Our [REDACTED] Investors include professional investors principally engaged in equity investments in the healthcare sector. The Sophisticated Investors of the Company include but are not limited to Sequoia Capital China Growth, which will be interested in approximately [REDACTED]% of the total issued share capital of our Company upon [REDACTED]. For more details, see “History, Development and Corporate Structure – [REDACTED] Investments”.

DILUTIVE EFFECT UNDER THE [REDACTED] EQUITY INCENTIVE PLAN

Assuming full vesting and exercise of all outstanding options and share awards under the [REDACTED] Equity Incentive Plan, the shareholding of our Shareholders immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised) will be diluted by approximately [REDACTED]%.

SUMMARY

SUMMARY OF KEY FINANCIAL INFORMATION

Summary of Consolidated Statements of Profit or Loss and Other Comprehensive Income

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

	Year ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Revenue	2,038	11,366
Gross profit	1,610	7,938
Other income and gains	9,517	105,696
Selling and distribution expenses	(6,292)	(35,934)
Research and development costs	(110,558)	(180,756)
Administrative expenses	(64,745)	(100,452)
Fair value losses on convertible redeemable preferred shares	(120,330)	(327,097)
Loss and total comprehensive loss for the year	<u>(319,581)</u>	<u>(555,836)</u>

We have incurred operating losses during the Track Record Period. Our loss before taxation was RMB319.6 million and RMB555.8 million for 2021 and 2022, respectively. Substantially all of our loss resulted from research and development costs and administrative expenses, with the increase as a result of the expansion of our business operations.

During the Track Record Period, substantially all of our revenue was generated from the sale of our scalp diseases and care products, skin diseases and care products, and Routine Skin Care Products. We expect to continue to generate most of our revenue from such source and expand our revenue sources upon the commercialization of our product candidates. In 2021 and 2022, we recorded revenue of RMB2.0 million and RMB11.4 million, respectively. During the Track Record Period, all of our revenue was derived from customers located in Greater China.

Gross profit represents our revenue less our cost of sales. Gross profit margin represents our gross profit as a percentage of our revenue. Our gross profit amounted to RMB1.6 million and RMB7.9 million in 2021 and 2022, respectively. Our gross profit margin reached 79.0% and 69.8% during the same years, respectively.

During the Track Record Period, our R&D costs consisted of staff costs, share-based payment expenses, acquisition/licensing-in expenses, third-party contracting costs, depreciation and amortization and others. In 2021 and 2022, we recorded R&D costs of RMB110.6 million and RMB180.8 million, respectively.

SUMMARY

Our fair value losses on convertible redeemable preferred shares represented the changes in fair value of the convertible redeemable preferred shares in relation to our [REDACTED] investments. In 2021 and 2022, we recorded fair value losses on convertible redeemable preferred shares of RMB120.3 million and RMB327.1 million, respectively. For more details regarding preferred shares, see the paragraph headed “History, Development and Corporate Structure – [REDACTED] Investments” in this Document. The fair value changes of convertible redeemable preferred shares adversely affected our financial performance in 2021 and 2022 and will continue to affect our financial performance during and subsequent to the Track Record Period until the conversion of preferred shares into ordinary shares upon [REDACTED].

For more details, see “Financial Information – Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income.”

Summary of Consolidated Statements of Financial Position

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

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Total non-current assets	93,156	301,380
Total current assets	1,401,725	1,145,425
Total assets	1,494,881	1,446,805
Total current liabilities	19,250	77,402
Total non-current liabilities	2,266,140	2,615,719
Total liabilities	2,285,390	2,693,121
Net current assets	1,382,475	1,068,023
Net liabilities	(790,509)	(1,246,316)

SUMMARY

We had net current assets of RMB1,382.5 million as of December 31, 2021, as compared to net current assets of RMB1,068.0 million as of December 31, 2022. This decrease was primarily due to an RMB362.0 million decrease in financial assets at FVTPL, which in turn was primarily due to the withdrawal of financial products and an RMB202.5 million decrease in time deposits over three months, primarily in relation to the maturity of our time deposits.

We incurred net liabilities of RMB1,246.3 million as of December 31, 2022, compared to net liabilities of RMB790.5 million as of December 31, 2021, primarily due to (i) losses of RMB555.8 million which in turn was primarily due to the expanded R&D activities in 2022 and (ii) share-based payment expenses of RMB100.0 million which is in line with the new grant of [REDACTED] Equity Incentive Plan in 2022. Upon the [REDACTED], our financial position will turn from net liabilities to net assets position with the automatic and irrevocable reclassification to equity of such Preferred Shares into ordinary shares.

For more details, see “Financial Information – Discussion of Certain Selected Items From The Consolidated Statements of Financial Position”.

Summary of Consolidated Statements of Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated:

	Year ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Net cash flows used in operating activities	<u>(159,877)</u>	<u>(236,190)</u>
Net cash flows (used in)/from investing activities	<u>(410,653)</u>	<u>462,065</u>
Net cash flows from/(used in) financing activities	<u>480,761</u>	<u>(10,249)</u>
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	<u>(89,769)</u>	<u>215,626</u>
Cash and cash equivalents at beginning of year	300,170	203,130
Effect of foreign exchange rate changes, net	<u>(7,271)</u>	<u>47,110</u>
CASH AND CASH EQUIVALENTS AT END OF YEAR	<u><u>203,130</u></u>	<u><u>465,866</u></u>

SUMMARY

Our net cash used in operation activities was RMB159.9 million and RMB236.2 million for 2021 and 2022, respectively. During the Track Record Period, we incurred negative cash flows from our operations, and substantially most of our operating cash outflows have resulted from our research and development costs.

During the Track Record Period, we derived our cash inflows from financing activities primarily from issue of convertible redeemable preferred shares. Our management closely monitors the use of cash and cash balances and has maintained a healthy liquidity for our operations. As our business develops and expands, we expect to generate more cash flow from our operating activities, through launching and commercializing our products and enhancing our cost containment capacity and operating efficiency.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, payment for property, plant and equipment, payment for intangible assets, and lease payments. We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] million in the [REDACTED], assuming no [REDACTED] is exercised and at an [REDACTED] of HK\$[REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]. Assuming an average cash burn rate going forward of 2.0 times the level in 2022, we estimate that our cash at bank and on hand as of December 31, 2023 will be able to maintain our financial viability for 39 months taking into account the estimated net [REDACTED] from the [REDACTED] and for 17 months without taking into account the estimated net [REDACTED] from the [REDACTED]. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

Key Financial Ratios

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

	As of December 31,	
	2021	2022
Current ratio ⁽¹⁾	72.8	14.8
Quick ratio ⁽²⁾	72.7	14.5

Notes:

- (1) Current ratio equals current assets divided by current liabilities as of the end of the year.
- (2) Quick ratio equals current assets less inventories and divided by current liabilities as of the end of the year.

Our current ratio decreased from 72.8 as of December 31, 2021 to 14.8 as of December 31, 2022, and our quick ratio decreased from 72.7 as of December 31, 2021 to 14.5 as of December 31, 2022, primarily due to a decrease in financial assets at FVTPL and an increase in trade and other payables, which in turn was primarily in relation to our expanded R&D activities.

SUMMARY

[REDACTED]

SUMMARY

DIVIDEND

After completion of the [REDACTED], our Shareholders will be entitled to receive dividends we declare. Our dividend policy will become effective upon [REDACTED]. Our dividend policy refers to any declaration and payment as well as the amount of dividends that will be subject to our Memorandum and Articles and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board of Directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. In addition, our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman counsel, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. Under the dividend policy, we intend to provide our Shareholders with interim or annual dividends as appropriate.

No dividend has been paid or declared by our Company since its date of incorporation and up to the end of the Track Record Period. Any declaration and payment as well as the amount of dividends will be subject to our Memorandum of Association and the Cayman Companies Act. The declaration and payment of dividends in the future will be determined by our Board of Directors, in its discretion, or the Shareholders in general meeting, and will depend on a number of factors, including our earnings, capital requirements, and overall financial condition. As advised by our Cayman counsel, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business (i.e. the solvency test as provided in the Cayman Companies Act). As advised by Harney Westwood & Riegels, the Company’s legal advisor on Cayman Islands laws, the financial position of accumulated losses does not prohibit us from declaring and paying dividends to our Shareholders, as dividends may still be declared and paid out of our share premium account notwithstanding our profitability, provided that we satisfy the solvency test set out in the Cayman Companies Act. There is no assurance that dividends of any amount will be declared to be distributed in any year.

If we pay dividends in the future, in order for us to distribute dividends to our Shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. For more details, see “Risk Factors – Risks Relating to Doing Business in China” in this Document.

SUMMARY

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no exercise of the [REDACTED] and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this Document. We intend to use the net [REDACTED] from the [REDACTED] for the following purposes:

- Approximately HK\$[REDACTED], representing [REDACTED]% of the [REDACTED], will be used for our Core Product CU-20401;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the [REDACTED], will be used to fund the continuing R&D activities of our Key Products, CU-40102 and CU-10201, including the planned clinical trials and the preparation of registration filings;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the [REDACTED], will be used to fund the continuing R&D activities of the other candidates in our pipeline, including the planned clinical trials and the preparation of registration filings;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the [REDACTED], for technology development and business development for pipeline expansion;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the [REDACTED], will be used for working capital and other general corporate purposes.

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

RISK FACTORS

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

- Our R&D, manufacturing and commercialization of CU-20401 may be adversely affected if the Joint Collaboration terminates.
- Negative results from off-label use of our future drug products could materially harm our business reputation, product brand name and financial condition and expose us to liability.

SUMMARY

- We face substantial competition for the development of our Core Product and other products, as our competitors may discover, develop or commercialize competing products earlier or more successfully than we do.
- Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete clinical development, obtain relevant regulatory approvals or achieve commercialization of our product candidates, or if we experience significant delays in any of the foregoing, our business, results of operations and financial condition may be adversely affected.
- Adverse events or undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval or cause product liability claims, which could expose us to costs and liabilities and adversely affect our operations and reputation.
- We have entered into collaborations or licensing arrangements and may seek collaborations or enter into licensing arrangements in the future. We may not realize the benefits of such collaborations or licensing arrangements, and disputes may arise between us and our collaboration partners which could harm our business.
- We are largely dependent on the sales of our commercialized products. If we fail to achieve or further promote the widespread market acceptance of our products, or if we fail to grow or retain our customers or consumer base, our business, results of operations and financial condition may be materially and adversely affected.
- Claims that our product candidates or the sale, distribution or use of our future products infringes, misappropriates or otherwise violates the patent or other intellectual rights of third parties could result in costly litigation, the outcome of which would be uncertain, or could require substantial time and money to resolve, even if litigation is avoided.
- Our business operations may in the future be affected by COVID-19 pandemic, and may be affected by other health epidemics or outbreaks of contagious diseases.

SUMMARY

[REDACTED] EXPENSES

[REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, [REDACTED] payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED]. [REDACTED] expenses for the [REDACTED] are estimated to be approximately HK\$[REDACTED], including (i) [REDACTED]-related expenses (including but not limited to [REDACTED] and fees) of approximately HK\$[REDACTED] and (ii) non-[REDACTED]-related expenses of approximately HK\$[REDACTED], comprising (a) fees and expenses of legal advisors and accountants of approximately HK\$[REDACTED] and (b) other fees and expenses of approximately HK\$[REDACTED], at an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED], which represents approximately [REDACTED]% of the gross [REDACTED] we expect to receive from this [REDACTED] assuming no Shares are issued pursuant to the [REDACTED]. RMB[REDACTED] (HK\$[REDACTED]) was recognized and charged to our consolidated statements of profit or loss and other comprehensive income for the year ended December 31, 2022. After December 31, 2022, approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss and other comprehensive income, and approximately HK\$[REDACTED] is expected to be charged against equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS

Impact of the COVID-19 Outbreak

Our Directors believe that, based on information available as of the date of this Document, the outbreak of COVID-19, including a surge in COVID-19 cases since December 2022 in China, is unlikely to result in a material adverse impact on our business, financial condition or results of operations, based on the following:

- *Our clinical development.* As of the Latest Practicable Date, we experienced a slight delay in the patient enrollment, data collection and data analysis for certain of our clinical trials. However, the outbreak of COVID-19 did not cause any termination of our clinical trials or necessitate the removal of any patients enrolled in our clinical trials or any material delay in registration progress. For example, since December 2022, the PRC government has lifted substantially all of its restrictive measures nationwide. Many regions faced a surge in COVID-19 cases following such lifting of restrictive measures. We have been closely monitoring the progress of our on-going clinical trials throughout China by maintaining frequent communication with the medical institutions that cooperate with us, and as of the Latest Practicable Date, we had not experienced and did not anticipate that there will be any material delay or suspension to our on-going clinical trials.

SUMMARY

- *Our daily operation.* Since the lifting of substantially all COVID-19 restrictions in China in December 2022, we experienced an increased number of COVID-19-related sick leaves from our employees in December 2022; however, we continued to maintain normal business operations. As of the Latest Practicable Date, the surge of COVID-19 infections in the cities where a majority of our employees are located has largely stabilized and our employees have been recovering and returning to work.
- *Commercialization.* Even though logistics fee rate increased in certain situations, there had not been material adverse impact on our results of operations and financial condition. In addition, we were unable to organize offline marketing in cities at certain times during the pandemic. Save for the aforementioned, our supply chain and cooperation with third parties remained largely unaffected by COVID-19 as of the Latest Practicable Date. As of the Latest Practicable Date, our services, marketing and business operations are no longer affected by COVID-19. Furthermore, on the basis of actions taken to date, our Directors believe that we have demonstrated our ability to respond swiftly to emergency circumstances and that the overall impact of COVID-19 on us was limited.
- *Regulatory affairs.* To the knowledge of our Directors, in December 2022, the evaluation process of the NMPA for applications were slower than usual, but the NMPA has resumed their normal review process since January 2023. We do not expect that our communications and filings with these authorities will be significantly affected by the outbreak of COVID-19.

Recent Regulatory Developments

Overseas [REDACTED]

On February 17, 2023, the CSRC promulgated Trial Administrative Measures of the 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 “Overseas Listing Trial Measures”) and relevant five guidelines, which became effective on March 31, 2023.

The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of the PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of the PRC domestic companies’ securities by adopting a filing-based regulatory regime.

According to the Overseas Listing Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that an overseas listing or offering is explicitly prohibited, if any of the following: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended

SUMMARY

securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholder(s) and the actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to make the securities offering and listing is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company’s controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

The Overseas Listing Trial Measures also provides that if the issuer both meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by the PRC domestic companies: (i) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies (the “**Size Test**”); and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are the PRC citizens or have their usual place(s) of residence located in mainland China. Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. The Overseas Listing Trial Measures also requires subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of the issuer(s) who have completed overseas offerings and listings.

At a press conference held for these new regulations, officials from the CSRC clarified that the domestic companies that have already been listed overseas on or before the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) shall be deemed as existing issuers, or the Existing Issuers. Existing Issuers are not required to complete the filling procedures immediately, and they shall be required to file with the CSRC when subsequent matters such as refinancing are involved. Further, according to the officials from the CSRC, domestic companies that have obtained approval from overseas regulatory authorities or securities exchanges (for example, a contemplated offering and/or listing in Hong Kong has passed the hearing of the Stock Exchange) for their indirect overseas offering and listing prior to the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) but have not yet completed their indirect overseas issuance and listing, are granted a six-month transition period from March 31, 2023. Those who complete their overseas offering and listing within such six months are deemed as Existing Issuers. Within such six-month transition period, however, if such domestic companies need to reapply for offering and listing procedures to the overseas regulatory authority or securities exchanges (such as requiring a new hearing of the Stock Exchange), or if they fail to complete their indirect overseas issuance and listing, such domestic companies shall complete the filling procedures with the CSRC. Based on the foregoing, if we cannot pass the hearing for the [REDACTED] on or before March 31, 2023,

SUMMARY

or if we pass the hearing for the [REDACTED] on or before March 31, 2023 but fail to complete this [REDACTED] and [REDACTED] on or before September 30, 2023, our PRC Legal Advisor is of the view that we will be required to complete the filing procedures with the CSRC in connection with the [REDACTED].

Based on the foregoing and as advised by our PRC Legal Advisor, we may be deemed as a PRC domestic company if our future financial performance meets the Size Test, and therefore subject to the Overseas Listing Trial Measures. If we fail to qualify as an Existing Issuer, we will be required to complete the filing procedures with the CSRC in connection with the [REDACTED] as required by the Overseas Listing Trial Measures. In any event, we will comply with the reporting obligations to the CSRC upon occurrence of material events after the [REDACTED] as required under the Overseas Listing Trial Measures.

Expected Increase in Net Loss

We expect to incur a significant increase in net loss for 2023 due to (i) the anticipated costs associated with increased research and development activities, (ii) fair value loss of financial liabilities at fair value through profit or loss, (iii) the anticipated increase in staff costs for administrative activities, and sales and marketing activities as we expand our business operations in 2023, and (iv) expenses in connection with the [REDACTED] incurred in 2023.

The Closure of Silicon Valley Bank

Silicon Valley Bank (“SVB”) was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. On March 12, 2023, the United States Department of the Treasury (the “Treasury Department”), Board of Governors of the Federal Reserve System and the FDIC issued a joint statement (the “Joint Statement”) that Secretary of the Treasury Department approved actions enabling the FDIC to complete its resolution of SVB in a manner that fully protects all depositors. According to the Joint Statement, depositors, including us, will have access to all of their deposits starting March 13, 2023.

As of March 13, 2023, we held approximately US\$1.9 million in cash at SVB, representing 2.9% of our total cash and cash equivalents as of December 31, 2022. We have resumed full access to our deposits with SVB starting from March 13, 2023, and expect to withdraw all such deposits by April 2023. Additionally, our cash and deposits are distributed across other reputable financial institutions not affiliated with SVB to the best of our knowledge and are readily accessible. Therefore, we do not believe the closure of SVB will have a material impact on our business, cashflow, R&D progress in China and our contractual obligation to Rejuven under CU-20401 Agreement.

No Material Adverse Change

Our Directors confirm that up to the date of this Document, there has been no material adverse change in our financial, operational or trading positions or prospects since December 31, 2022, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this Document.