#### **OVERVIEW**

We are an R&D-driven, dermatology-focused biopharmaceutical company dedicated to developing comprehensive solutions that are tailored to meet the diverse and evolving needs of patients and consumers in the broader dermatology treatment and care market. As of the Latest Practicable Date, we had built a broad portfolio of nine products and product candidates, targeting the four main sectors of the broader dermatology treatment and care market, namely localized adipose accumulation management medication, scalp diseases and care, skin diseases and care and topical anesthesia. We are developing five clinical-stage and four pre-clinical-stage drug candidates. Among the five clinical-stage drug candidates, two products have commenced pilot commercialization in Lecheng, Hainan. We also distributed two commercialized products developed by overseas collaboration partners.

According to Frost & Sullivan, the size of China's broader dermatology treatment and care market has increased rapidly in recent years and is expected to grow further in the foreseeable future, primarily driven by the increasing prevalence of dermatology diseases in China, growing disposable income per capita of Chinese residents, rising skin disease and care management awareness and advancing dermatological therapies. According to Frost & Sullivan, the market size of the broader dermatology treatment and care market in China reached RMB471.8 billion in 2021, and is projected to grow to RMB1,037.5 billion in 2030, representing a CAGR of 9.2%. Despite the promising growth trend, the broader dermatology treatment and care market in China is still at a nascent stage and remains largely underpenetrated. Additionally, the current commercial offerings in China are not aligned with customer needs, and most dermatology companies in China lack the comprehensive capabilities and systemic operational management to timely deliver one-stop solutions covering the entire treatment and care cycle to customers. The combination of these factors created significant unmet customer needs and entry barriers in the market.

We are one of the few players in the broader dermatology treatment and care market in China equipped with fully integrated capabilities. We have applied a customer-centric approach to bolster our product candidates and expand our integrated capabilities to the entire broader dermatology treatment and care industry value chain. Our platform spans from the early phase of identifying demands, developing core technologies, managing clinical trials and product registrations, to the manufacturing and marketing of products. We believe our integrated capabilities give us the agility to formulate our innovation, registration, commercialization and product optimization strategies that can navigate us through rapidly changing market needs, enabling us to improve pipeline viability and expedite product development cycle at lower costs.

With robust in-house R&D capabilities and powered by our proprietary CATAME<sup>®</sup> technology platform, we have developed our product portfolio to meet the diverse unmet medical needs of physicians and patients. The CATAME<sup>®</sup> technology platform improves drugs to achieve topical or transdermal delivery by developing micron and nano-sized particulates, as well as evaluating formulation quality and stability, and performing cutaneous

pharmacokinetic analysis. Our platform also helps design the most suitable product formats that are key to specific and successful drug delivery. Through this platform, we have built a competitive product pipeline of creams, sprays, ointments, aerosol foams and other dosage forms.

Aside from our robust in-house R&D capabilities, we also strategically expand our pipeline through active collaborations and licensing from third parties. Leveraging our extensive collaborations and development capabilities, we believe we can serve as the partner-of-choice for biopharmaceutical companies that wish to tap into the rapidly growing China market and are looking for local expertise and network. We have established cooperative relationships with reputable scientific advisors and third party institutions to effectively develop new, clinically effective and commercially attractive product candidates and maintain a stable and risk-balanced pipeline.

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

aunt t (S.S.) A A A A A A A A A A A A A A A A A A A	Cand	Candidate	Active Ingredients & Formulation	Indication	OTC / Prescription Drugs	Commercial Rights	Source	Pre- Clinical	IND Phase I	se I Phase	Phase II Phase III	Registration Commer	Commercialization	Upcoming Milestone	Expected Commercial Launch	NMPA Registration Classification <sup>10</sup>
(Motional Fig.     Antopositi   Description data   Control   Intersted   Application	401²★ Reco	Reco	mbinant mutant genase	Submental Adipose Accumulation (Submental Fat) Abdominal Adipose Accumulation	Prescription drug	Asia	Acquired						16, 06	initiate Phase II in iQ2023 Complete Phase I in :024	2028 2028	_
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OTCGotalSelf.NDANDA submission203Prescription drugGlobaldevelopedNNNNDPrescription drugGlobaldevelopedNNDNDNDNPrescription drugGreater China'InternedNDNDNDNDPrescription drugGreater China'InternedNDNDNDNDNDPrescription drugGreater China'InternedNDNDNDNDNDPrescription drugSubfisconNDNDNDNDNDNDPrescription drugSubfisconNDNDNDNDNDNDPrescription drugSubfisconNDNDNDNDNDNDPrescription drugSubfisconNDNDNDNDNDNDPrescription drugSubfisconNDNDNDNDNDNDPrescription drugSubfisconNDNDNDNDNDNDPrescription drugSubfisconSubfisconNDNDNDNDNDPrescription drugSubfisconSubfisconSubfisconSubfisconSubfisconSubfisconSubfisconPrescription drugSubfisconSubfisconSubfisconSubfisconSubfisconSubfisconSubfisconSubfisconSubfisconPrescription drugSubfisconSubfisconSubfisconSubfisconSubfisconSubfiscon </td <td>TC CU-40101<sup>4</sup> th ag</td> <td>L H B</td> <td>ppical small molecule yroid hormone recept onist liniment</td> <td></td> <td>Prescription drug</td> <td></td> <td>In-licensed</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>04</td> <td>Complete Phase I in 2024</td> <td>TBD</td> <td>-</td>	TC CU-40101 <sup>4</sup> th ag	L H B	ppical small molecule yroid hormone recept onist liniment		Prescription drug		In-licensed						04	Complete Phase I in 2024	TBD	-
Prescription drug   Global   developed   TBD   TBD   TBD     s   Prescription drug   Greater Chinal'   Incluended   NDA submission to NMPA in 4Q2023   4Q3024   TBD     s   Prescription drug   Greater Chinal'   Incluended   NDA submission to NMPA in 4Q2023   4Q3024   TBD     Prescription drug   Greater Chinal'   Incluended   NDA submission to NMPA in 2Q2024   TBD     Prescription drug   Greater Chinal'   Incluended   NDA submission to NMPA in 2Q2024   TBD     Prescription drug   Greater Chinal'   Incluended   NDA submission to NMPA in 2Q2024   TBD     Prescription drug   Greater Chinal'   Aqtined   NDA submission to NMPA in 2Q2024   TBD     Prescription drug   Greater Chinal'   Aqtined   NDA submission to NMPA in 2Q2054   TBD     Prescription drug   Greater Chinal'   Aqtined   NDA submission to NMPA in 2Q2054   TBD     Prescription drug   Greater Chinal'   Aqtined   NDA submission to NMPA in 2Q2054   ZD274     Prescription drug   Greater Chinal'   Aqtined   NDA submission to NDA submission to NDA submission to NDA submission to NDA submission to NDA submission to NDA submissi	CU-40103 Tc	ŭ	ppical minoxidil foam	Alopecia	OTC		Self- developed						14	ANDA submission o NMPA in 3Q2024	2025	m
Prescription drug   Greater China <sup>4</sup> In-licensed   Ac2024   4Q204     Prescription drug   Vareater China <sup>4</sup> In-licensed   In-licensed </td <td>CU-40104 T</td> <td>- F</td> <td>opical dutasteride agen</td> <td>t Androgenic Alopecia</td> <td>Prescription drug</td> <td></td> <td>Self- developed</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>I</td> <td>ND application ubmission to NMPA in 4Q2024</td> <td>TBD</td> <td>6</td>	CU-40104 T	- F	opical dutasteride agen	t Androgenic Alopecia	Prescription drug		Self- developed						I	ND application ubmission to NMPA in 4Q2024	TBD	6
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	CU-30101 <sup>8</sup> L		Localized topical lidocaine and tetracaine cream			Greater China <sup>®</sup>	Acquired						U	Commence Phase III n 2Q2023	2026	ņ

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# **BUSINESS**

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**BUSINESS** 

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#### 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. 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 significantly 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 the asset transfer of CU-20401. The formulation of CU-20401 includes recombinant mutant collagenase, trometamol, sucrose, calcium chloride, 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 the completed Phase I clinical trial is that its result 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 the 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. Growing prevalence of androgenetic alopecia in China presents market potential for scalp disease treatment and subsequent scalp care maintenance. CU-40102's topical finasteride formulation is applied by spraying onto the scalp. We are currently conducting a Phase I clinical trial for PK and a registrational Phase III clinical trial for CU-40102 for androgenetic alopecia in Mainland China, and we have commenced pilot commercialization of CU-40102 in Lecheng, Hainan.
- *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-40101 is differentiated from current androgenetic alopecia treatment in its mechanism of action and the potential to be used in both male and female patients. We are currently running a Phase I dose escalation trial in China to evaluate the safety and tolerability of CU-40101 as a therapeutic agent in promoting hair growth in patients with androgenetic alopecia.

- *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-40103 is expected to adopt a differentiated foam formulation and become an addition to the existing minoxidil tinctures and liniments in the market. It has a less greasy texture that enables better user experience. We are currently conducting the pre-clinical study of CU-40103.
- *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. We are currently conducting the pre-clinical study of CU-40104.

#### 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 ("Foamix") in April 2020. Foamix was a subsidiary of Menlo Therapeutics Inc. (Nasdaq: MNLO), whose corporate name was changed to VYNE Therapeutics Inc. (Nasdaq: VYNE) in late 2020. The FDA approved CU-10201 for the treatment of moderate to severe acne vulgaris in the U.S. in 2019 with Foamix as the market authorization holder and brand name of Amzeeq<sup>TM</sup>. Minocycline exhibits broad-spectrum antibacterial activity. The currently available minocycline products are mostly oral medications. With a topical formulation, CU-10201 can be delivered to the acne lesions, thereby significantly reducing systemic exposure and incidence of associated adverse events as observed in the Phase III clinical trial in U.S. We are currently evaluating the therapeutic potential of CU-10201 for the treatment of moderate to severe acne vulgaris in the Phase III clinical trial in China.
- *CU-10101.* CU-10101 is an in-licensed non-hormonal, small molecule alternative drug targeting atopic dermatitis. We in-licensed CU-10101 from Wuhan Yingnashi Pharmaceutical Co., Ltd. in November 2019. For atopic dermatitis, the therapeutic options are limited and mainly include corticosteroids, calcineurin inhibitors, systemic immunosuppressants, and targeted biologics and small-molecule drugs. Topical steroids are the most commonly prescribed therapies for atopic dermatitis. Most targeted biologics and small molecule drugs for atopic dermatitis require subcutaneous or oral administration, where systemic exposure causes a higher risk of side effects and lower patient compliance than topical treatments. The first FDA-approved topical JAK inhibitor

for the treatment of atopic dermatitis, opzelura (ruxolitinib) cream, developed by Incyte, can only be used for short-term and non-continuous chronic treatment of patients with mild to moderate atopic dermatitis. The non-hormonal properties of CU-10101 potentially reduce the side effects and restrictions associated with corticosteroids and it features a topical formulation that can reach the affected areas directly. We are currently conducting the pre-clinical study of CU-10101.

• *CU-10401.* CU-10401, an acquired aryl hydrocarbon receptor (AhR) targeted nonsteroidal 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. Current treatments for psoriasis include topical therapy, phototherapy and systemic therapies. 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. Compared with another commonly used topical drug, calcipotriol, tapinarof has a lower recurrence rate without risks of elevated serum calcium which can be caused by calcipotriol. We are currently conducting the pre-clinical study of CU-10401.

# **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. Compounded lidocaine and prilocaine formula is currently the only marketed topical compounded anesthesia cream in China. CU-30101's lidocaine and tetracaine combination formulations may produce rapid and long-lasting anesthetic effects due to its ingredients' pharmacokinetic properties. Lidocaine diffuses more rapidly, and more extensively than tetracaine, whereas tetracaine, a long-acting amino acid ester, is more lipophilic than lidocaine and can be concentrated in the topical stratum corneum. Systemic absorption of the anesthetic component ingredients is also limited from the topical cream formulation. We received the NMPA's IND approval for CU-30101 in November 2022.

# **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. CUP-MNDE is refreshing to be applied to the scalp by its low concentration propylene glycol formulation technology. The key ingredient of CUP-MNDE is minoxidil, which can promote hair growth by relaxing the muscular walls of blood vessels, allowing blood, nutrients and oxygen to flow more easily to the scalp and hair follicles. CUP-MNDE has been commercialized by its original developer Laboratoires Bailleul in Europe and according to Frost & Sullivan, it is the best-selling minoxidil brand in terms of volume sold in Italy, Portugal and Belgium in 2021.

• *CUP-SFJH*. CUP-SFJH is a commercialized hair growth serum featuring a non-hormonal formula of natural plant extracts developed by Van Montfort Laboratories B.V. ("VML"). We have exclusive distribution rights to develop the distribution and marketing of CUP-SFJH in Mainland China. CUP-SFJH is used for hair loss prevention and hair quality improvement. With its liposome technology, CUP-SFJH can transport nutrients to the root of the hair follicles through the double-layer phospholipid membrane wrapping.

#### 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

We are committed to providing comprehensive solutions across different therapeutic areas within the rapidly growing broader dermatology treatment and care market in China. China's broader dermatology treatment and care market grew from RMB300.4 billion in 2017 to RMB471.8 billion in 2021, representing a CAGR of 11.9%, and is expected to grow to RMB670.2 billion in 2025 and RMB1,037.5 billion in 2030, representing a CAGR of 9.1% from 2025 to 2030, according to Frost & Sullivan. Despite the rapid growth, the per capita annual spending on broader dermatology treatment and care in China remains low due to the lack of comprehensive, effective and alternative solutions. In 2021, the per capita expenditure on broader dermatology treatment and care in the U.S., Japan and South Korea reached RMB1,828.0, RMB1,417.3 and RMB1,406.9, respectively. By comparison, the per capita expenditure of broader dermatology treatment and care in China in 2021 was RMB334.0.

According to Frost & Sullivan, China's broader dermatology treatment and care market is distinguished by a unique set of consumer behaviors, including higher willingness to pay, more frequent repurchase pattern and higher yet unsatisfied demand for comprehensive, effective and alternative product offerings. Due to the nature of dermatology conditions, patients experiencing different stages of the disease will also require differentiated medications, sometimes in combination, to realize optimal results.

Furthermore, there has been a misalignment between product offerings and medical needs in China's broader dermatology treatment and care market. We believe that some marketed products are unable to either effectively address dermatological problems specific to the Chinese population or provide distinctive and comprehensive solutions specific to each treatment stage. In addition, a large number of dermatology companies in China do not possess full platform capabilities from early drug discovery to commercialization, so it has been challenging for them to quickly respond to shifts in market demand and deliver comprehensive solutions to customers efficiently. This ultimately leads to unmet customer demand and a proliferating market with a group of products with little or no apparent clinical benefit. Alternative and effective products are urgently needed for the growing Chinese population with increasing per capita disposable income.

We are one of the few players in the broader dermatology treatment and care market in China equipped with fully integrated capabilities. We have a comprehensive product pipeline of nine products and product candidates, including five clinical-stage and four pre-clinical stage drug candidates to fulfill market demands. Our success is attributable to our integrated capabilities, continuous innovation driven by our customer-centric philosophy and proprietary CATAME<sup>®</sup> technology platform, comprehensive pipeline and experienced management team. We believe that we are well-positioned to capitalize on the projected growth of China's broader dermatology treatment and care market and continue to scale our business and expand our market share.

#### Integrated Capabilities Covering the Entire Broader Dermatology Treatment and Care Industry Value Chain

Since our inception, we have taken a customer-centric approach and expanded our operational capabilities around providing safe and comprehensive therapeutic solutions. We have designed a full value chain product development framework and built our R&D, registration, commercialization and product optimization strategies based on unmet medical needs. Our multi-disciplinary teams come from diverse backgrounds and are well equipped with insightful industry know-how and proven track record that allow us to tap into critical product development stages to improve product viability and success rate. We expanded our product portfolio through in-house R&D as well as capitalizing on opportunities to license-in alternative product candidates.

At the product discovery stage, our R&D team conducts in-depth market research capitalized on our broad network across the medical industry and academia, in order to further confirm medical needs and provide insights for our product development. We also benefit from the network and industry resources of our prominent shareholders with deep biotech expertise. Our business development team has a track record of successfully bringing in drug candidates with high clinical value to expand and complement our pipeline. At the clinical development stage, we believe our efficient clinical operation capabilities and fast registration strategy lay solid foundations for prompt commercial launch. As of the Latest Practicable Date, we had advanced five candidates into clinical trials in China. At the commercial stage, our experienced sales team fully understands customer needs and is able to conduct targeted marketing to acquire users and increase customer stickiness.

For manufacturing, the construction of a commercial-scale GMP factory with three drug product production lines in Jiangsu province was completed in February 2023. The three production lines cover topical cream, ointment, aerosol, and foam products with a planned annual production capacity of approximately a total of five million doses of CU-10101, CU-40103, CU-40104, CU-10401 and CU-30101. The site is expected to commence operation in the first quarter of 2023. We believe that upon completion the production capacity of this factory can support our clinical trials and near-term commercialization plans for our drug candidates. The flow and control of the entire manufacturing facility are designed to be compliant with the latest cGMP requirements so that our production can meet the clinical and marketing approval requirements of various drug regulatory authorities, including the NMPA, FDA and European Medicines Agency.

We have adopted a well-tailored commercialization strategy to penetrate the broader dermatology treatment and care market in China. We believe that our commercialization capabilities will continue to be robust driven by our deep expertise in sales and marketing, close collaboration with e-commerce platforms, and growing sales and distribution network. We are in preparation for launching our alternative pipeline products and building a medical commercialization and marketing platform to nurture strong strategic cooperative relationships with top hospitals.

The successful pilot commercialization of our Key Product CU-10201 is a recent demonstration of our fully integrated capabilities. We initially identified an unmet need for acne treatment in China through academic research and validated that a formulation change to the proven molecule minocycline could be the potential solution. Leveraging our broad network of relationships with pharmaceutical companies and deep expertise in transdermal technology, we started the conversation with Vyne Therapeutics in 2019 for its minocycline portfolio and were successful in obtaining exclusive development and commercialization rights for CU-10201 in Greater China in April 2020. We strategically designed and diligently ran the clinical trials of CU-10201 with the aim of achieving efficient execution and optimal data quality. We maintained constructive communications with the regulatory authorities to seek to accelerate the approval process of CU-10201. In Lecheng, Hainan, we brought CU-10201 from initial assessment to pilot commercialization in approximately three months.

# Continuous Innovation Driven by Our Customer-centric Philosophy and Proprietary CATAME<sup>®</sup> Technology Platform

Our continuous innovation is driven by our customer-centric philosophy, in-depth scientific insights, and knowledge of the latest clinical practices and unmet medical needs. We have strategically expanded our R&D horizon and product offerings by applying our accumulated skills and product development capabilities in new molecule synthesis and transdermal drug delivery. Our efficient R&D process is supported by a seamless collaboration of experienced internal teams and external scientific committees, resulting in an end-to-end R&D capability across the industry value chain.

Our CATAME<sup>®</sup> technology platform is a comprehensive platform that facilitates the development of products that cover major types of dermatological diseases. The CATAME<sup>®</sup> platform 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 & Efficacy Evaluation (EVEE) platform. Our CATAME<sup>®</sup> technology platform helps customize transdermal delivery capabilities for drugs, develop micron and nano-sized particulates, evaluate formulation quality and stability and perform cutaneous pharmacokinetic analysis. On the other hand, our platform also helps design the most suitable product formats that are key to specific and successful drug delivery. Through this platform, we have built a competitive product pipeline of creams, sprays, ointments, aerosol foams and other dosage forms.

Our experienced in-house R&D team comes from a variety of medical backgrounds and has 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 integrated team spans market intelligence, drug discovery, clinical development, quality control, 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. As of the Latest Practicable Date, we had obtained six IND approvals and are running and preparing three Phase III clinical trials. We have accumulated comprehensive experience and strong ability to complete the entire drug development process from pre-clinical research to clinical development and to NDA filings.

We have established relationships with reputable scientific advisors and third-party institutions where we closely collaborate with experienced physicians to identify and develop commercially attractive product candidates that better address unmet medical needs in the broader dermatology treatment and care industry. For example, the principal investigators for the clinical trials of our skin disease products include prominent acne and pigmentosis specialists in China and members of the Chinese Medical Association.

Building upon our customer-centric philosophy and integrated technology platforms, we demonstrated our ability for continuous innovation by establishing a pipeline of nine products and product candidates within three years of inception, of which five products are in registrational clinical trials.

#### **Comprehensive Pipeline Captures Large Market Potential and Unmet Needs**

We have designed and assembled a comprehensive and differentiated portfolio to target diseases with highly unmet medical needs across the four major dermatological therapeutic areas: localized adipose accumulation management medication, scalp diseases and care, skin diseases and care and topical anesthesia. Our product matrix provides comprehensive solutions to address the diverse unmet medical needs from consumers or patients during different states of the disease cycle. Additionally, our comprehensive offering includes OTC products that address distinctive demands from a wide range of population groups as their needs evolve with disease progression or improvement to gain customer stickiness. In addition, our portfolio is a risk-balanced combination of commercialized products, alternative products with proven pathways candidates.

#### Scalp Diseases and Care

Currently widely accepted therapies for scalp diseases include minoxidil, finasteride and cyproterone, which have a number of treatment restrictions. Finasteride is only available in oral form with potential undesired side effects and is indicated for male patients only. The primary concern of current topical minoxidil offerings is their unsatisfactory efficacy, uncertain mechanism and accelerated hair loss during the initial treatment stage. We believe that our scalp disease products are well positioned to address these treatment limitations and capture the growing scalp diseases and care market in China, the size of which is expected to

reach RMB203.5 billion in 2030, according to Frost & Sullivan. We have developed six comprehensive and complementary topical products and product candidates for scalp diseases and care, including our Key Product CU-40102 (topical finasteride spray), CUP-MNDE (topical minoxidil spray), CU-40103 (topical minoxidil foam), CU-40101 (topical small molecule hormone receptor agonist liniment), CU-40104 (topical dutasteride agent) and CUP-SFJH (topical natural plant extracts serum) to cover the entire cycle of scalp diseases. Our scalp diseases and care product offerings form a variety of treatment regimes and care solutions that cater to consumers with different needs. Previous studies showed that combination of minoxidil and finasteride, regardless the concentration level, indicates a greater improvement of hair density compared to topical minoxidil alone. We believe CU-40102 and CUP-MNDE complement each other and maximize synergy in the treatment of alopecia.

Our key scalp disease product CU-40102 is the first and only topical finasteride product approved for androgenetic alopecia treatment globally and the only topical finasteride under clinical development in China. Finasteride is currently the mainstream and the only available oral form treatment for alopecia in China but is often associated with systemic side effects. Unlike oral finasteride, CU-40102's topical formulation allows patients to apply the drug directly to the surface of the scalp, thereby maintaining a high concentration at the affected site while reducing the side effects commonly associated with oral formulations. CU-40102's topical formulation is difficult to develop or replicate due to finasteride's distinctive chemical properties, creating a high technology barrier. In the registrational Phase III clinical trials sponsored by Polichem S.A., data showed that a large percentage of patients receiving CU-40102 treatment improved their hair condition compared to the placebo group. Our Phase III clinical trial of CU-40102 for the treatment of androgenetic alopecia in Mainland China has completed patient enrollment. We expect to complete primary endpoint read-out for the Phase III clinical trial in the fourth quarter in 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in 2024.

CUP-MNDE, another of our scalp disease products, is a commercialized OTC minoxidil spray. Minoxidil is an FDA-approved medication that improves hair growth and slows down the alopecia process. Topical minoxidil has achieved the highest market share of 18.2% for the treatment of scalp disease in the U.S., where it is the most commonly used topical drug to treat alopecia in the U.S. The key ingredient of CUP-MNDE, minoxidil, promotes hair follicle growth and is refreshing to be applied to the scalp. Compared to other topical forms, our minoxidil spray improves the solubility of minoxidil, which facilitates the sustained absorption of the active ingredient on the scalp. It also ensures accurate dosing and enhances transdermal penetration and follicular delivery to achieve the desired outcome.

#### Skin Diseases and Care

Current treatments for common skin diseases include, among others, glucocorticoid, antibiotics and isotretinoin. However, due to drug resistance from long treatment duration, the lack of novel and effective treatments and the unclear pathology of skin diseases, current therapies are unlikely to generate meaningful or durable response and patients are generally

prone to relapse. Additionally, common side effects associated with glucocorticoid, antibiotics and isotretinoin are likely to cause poor patient compliance. We are currently developing three skin disease products, including Key Product CU-10201 for the treatment of moderate to severe acne vulgaris, CU-10101 for the treatment of atopic dermatitis and CU-10401 for the treatment of psoriasis, to capture the growing market of skin diseases and care products in China, which is expected to reach the size of RMB740.2 billion in 2030.

Our key skin diseases and care product CU-10201, is the first and only topical minocycline approved for acne vulgaris treatment globally and the only topical minocycline under clinical development in China. Minocycline is a tetracycline antibiotic used to treat bacterial infections and acne vulgaris. Compared to other major anti-acne antibiotics, topical minocycline foam has fewer side effects, a lower rate of drug resistance, and likely higher patient compliance. In addition, the highly lipophilic nature of minocycline allows it to concentrate in hair follicles and sebaceous glands. In a U.S. Phase III randomized study sponsored by Foamix Pharmaceuticals, Inc., CU-10201 was shown to have superior improvement in inflammatory lesion count at week 12 and consistently reduced inflammatory acne over the 12-week study period in the CU-10201 treatment arm compared with the placebo treatment arm. CU-10201 has also demonstrated its potential to overcome side effects commonly seen in conventional oral drugs due to lower systemic exposure. In a pharmacokinetic study run by Foamix Pharmaceuticals, Inc., minocycline exposure was 730 to 794 times lower after topical application of four grams per day of the maximum use dose of CU-10201 than after a single oral dose of solydyn, a minocycline hydrochloride drug. We, as the sponsor, are currently conducting a bridging Phase III clinical trial for CU-10201, and we have commenced pilot commercialization of CU-10201 in Lecheng, Hainan. We expect to complete the primary endpoint read-out for the Phase III clinical trial in the first quarter of 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in the fourth quarter of 2024.

# Localized Adipose Accumulation Management Medication

Current treatment for localized adipose accumulation includes, among others, localized adipose accumulation management medications, energy-based fat reduction procedures and liposuction procedures. Compared with other treatment procedures, localized adipose accumulation management medication is characterized by low invasiveness with high patient compliance, less postoperative pain, ease of use, and speedy recovery. According to Frost & Sullivan, there are no approved localized adipose accumulation management medications in China. We believe that CU-20401 is well-positioned to capture the growth of the market size of localized adipose accumulation management medications in China for labelled use, which is expected to reach RMB2,439.9 million in 2030, according to the same source.

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. CU-20401 adopts an alternative mechanism of action where it can act selectively on fat cells attached to the extracellular matrix of adipose tissue. CU-20401 acts as a collagenase that degrades extracellular matrix collagen in the subcutaneous fat layer, leading to apoptosis of adipocytes. It also releases the collagen network surrounding the fat cells, thereby inducing their apoptosis and achieving a sculpting effect while reducing treatment pain. The mechanism also differentiates CU-20401 from its competing products which are largely deoxycholic acid based solutions that cause indiscriminate destruction of fat and surrounding cells and result in as swelling, bruising, pain and numbness at the treatment site. Our completed Phase I clinical data shows that CU-20401 can reduce excessive adipose accumulation, a condition in which body fat has accumulated to the extent that it affects one's appearance and might impair health. 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 the Phase II clinical trial of CU-20401 for submental adipose accumulation (submental fat) in the third quarter of 2023. As a local and minimally invasive treatment, CU-20401 exhibited low systemic drug exposure in blood.

#### Topical Anesthesia

Topical anesthesia offers better patient comfort and eliminates the use of invasive needles as well as associated pain and risk such as distortion of wound margin and intravascular injection, demonstrating their potential for broader and safer clinical application. Currently, only two topical anesthetics are approved for puncture and superficial dermatological procedures and more than 25 topical anesthetics are under development in China, according to Frost & Sullivan. Most of those competing are compounds of lidocaine and prilocaine. CU-30101 is a generic lidocaine/tetracaine compound. Studies have shown that lidocaine and tetracaine cream treatments provide better pain relief, with more subjects (75%) reporting adequate pain relief compared to subjects (67.5%) who received lidocaine and prilocaine treatments after 30 minutes of topical anesthesia treatment. In addition, the application of lidocaine/prilocaine cream requires plastic occlusion, whereas lidocaine/tetracaine cream is self-occlusive, which is more convenient for the user. We believe those advantages enable CU-30101 to compete with other approved and clinical-stage topical anesthesia in China, and it may capture the topical anesthesia market in China, the size of which is expected to reach RMB2,690.4 million in 2030, according to Frost & Sullivan.

#### **Experienced Management Team**

Members of our management team, who have extensive multinational pharmaceutical company and multi-disciplinary backgrounds and rich domestic experiences, are critical to our success.

Our founder, executive Director and chief executive officer, Ms. Zhang Lele, has worked in the pharmaceutical industry for approximately 20 years, accumulating a wealth of first-hand experience in the industry with a proven track record of success. She served as an assistant business development manager at Shanghai Novartis Trading Co., Ltd (上海諾華貿易有限公 司), head of strategic alliances at Eisai China Inc. (衛材(中國)藥業有限公司) and head of strategic projects department at Santen Pharmaceutical (China) Co., Ltd. (參天製藥(中國)有限 公司).

Our executive Director and chief financial officer, Mr. Huang Yuqing, has rich experience in the investment and capital market fields. Mr. Huang previously served as the lead analyst for Greater China Healthcare Research at Jefferies Hong Kong Limited and was recognized as one of the Top Three Best Analysts in the healthcare industry by the Institutional Investor All-China Research Team Survey in 2017. Mr. Huang also worked as the chief financial officer and chief business officer of Kintor Pharmaceutical Limited (9939).

Our chief medical officer, Mr. Zhu Qi, has over 20 years of experience at multinational pharmaceutical companies, including Roche, Biogen, AbbVie and Menarini, with rich experience in pharmaceuticals. He is well-versed in product life cycle management, including new product evaluation and development, registrational clinical trial, post-market study and pharmacovigilance.

Our senior vice president of R&D department, Dr. Lei Lei, is a senior specialist in pharmaceutical development. Dr. Lei has rich experience in the development of medical products at multinational pharmaceutical companies. He was the former principal scientist at Shanghai Johnson & Johnson Pharmaceuticals Ltd (上海強生製藥有限公司). Dr. Lei authored more than 20 international academic papers and is leading a Shanghai New Drug Support Fund Project, a science collaboration project with The Science and Technology Commission of Shanghai Municipality for innovative drug development on scalp diseases.

Our senior vice president of regulatory affairs, Ms. Zhang Chunna, has approximately 10 years of experience as the head of registration at a multinational pharmaceutical company. She is experienced with drug registration regulation and led the registration of multiple products. She also has seven years of experience in developing novel drug delivery system and pharmaceutical industrialization and participated in the project of the State High-Tech Development Program (國家高技術研究發展計劃).

Our senior vice president of manufacturing and quality control department, Ms. Xu Jingxin, has more than 20 years of experience in quality assurance at multinational pharmaceutical companies and leading domestic companies, including Pfizer, BeiGene and AstraZeneca. With her exceptional quality and risk management capabilities, she has led the quality control and management upgrade of production facilities.

Our senior vice president of finance and integrated management department, Mr. Wu Jiaru, has rich experience in finance management and analysis. Mr. Wu is primarily responsible for decision making and executive oversight of finance, information technology and procurement operations. Mr. Wu previously served as a senior system controller in Giti Tire (China) Investment Company Ltd. (佳通輪胎(中國)投資有限公司) and a reporting expert in KaVo-Sybron Dental (Shanghai) Co. Ltd (卡瓦盛邦(上海)牙科醫療器械有限公司).

Our management team have rich cross-industry experience, covering numerous disciplines, including finance, CMC and pharmaceutical with an average industry experience of over 10 years. Their industry insights enable us to solidify our market position and optimize our performance.

We are also supported by our strong external scientific committees consisting of leading scientists, physicians and industry veterans.

#### STRATEGIES

# Focus on Customer Needs and Utilize Integrated Industrial Capabilities to Provide Alternative Dermatology Management Solutions

Leveraging our integrated capabilities across the entire broader dermatology treatment and care industry, we are dedicated to providing safe and comprehensive dermatology treatment and care solutions. We will continue to strengthen our inter-department and external collaborations. We will also enhance collaborations with our partners to seek new opportunities for expanding our product pipeline.

We aim to provide one-stop and comprehensive dermatology management solutions to our customers. In particular, currently, there are few adipose tissue management products approved by NMPA, but those are cosmetic products that are approved for topical application only. In contrast to cosmetics products, our Core Product CU-20401 is developed to be a medical product prescribed by qualified medical institutions. It is indicated for adipose accumulation, which is a typical manifestation of metabolic diseases such as obesity and overweight into human body in China.

The continued strengthening and expansion of our CATAME<sup>®</sup> technology platform is one of our top priorities. With deep insights into the mechanisms of dermatological diseases and medical needs, our R&D strategy focuses on topical and transdermal formulation as well as dermal drug delivery technologies, which enable us to meet customer demands precisely, safely and rapidly. We intend to explore other potential alternative platform technologies, which are easily scalable to continuously empower our new product offerings. Through such platform technologies, we believe we will be able to develop new products with higher efficiency, lower cost and reduced scientific and commercial risks. With accelerated product iterations, we are better positioned to maintain our competitive edges.

We will strengthen our market demand identification capabilities. Our R&D, medical and marketing teams will work together to identify unmet needs and changes in customer preferences through a combination of macro and micro models such as data mining and market research to guide our product development strategies. We will also enhance our manufacturing capacities and multi-dimensional commercialization capabilities. Other than the manufacturing facilities under construction, we plan to enhance our production capacities in line with the expansion of our product pipeline. Unique features of the broader dermatology treatment and care industry require us to possess strong sales and marketing capabilities through enhanced relationships with customers, patients, physicians and medical institutions. We will expand our external collaboration network, strengthen our sales and marketing capabilities, and work closely with renowned physicians to conduct product demonstrations and provide training to them.

To ensure execution across corporate functions, we will continuously recruit, develop and retain talents with a spectrum of integrated skills. Our targeted talents including experienced scientific, medical or business practitioners.

#### Continue to Advance the Clinical Development of Our Product Portfolio

Our R&D, medical and registration teams will continue to work closely together to develop tailored and efficient clinical development programs for our product candidates, which allows us to efficiently commercialize products. In particular:

#### Localized Adipose Accumulation Management Medication

• *Core Product CU-20401.* We completed a Phase I clinical trial of CU-20401 for the treatment of submental adipose accumulation (submental fat) in November 2022 and are conducting another Phase I clinical trial for abdominal adipose accumulation (abdominal 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 the Phase II clinical trial of CU-20401 for submental adipose accumulation (submental fat) in the third quarter of 2023.

# Scalp Diseases and Care

- *Key Product CU-40102.* We are currently conducting a Phase I clinical trial for PK and a registrational Phase III clinical trial for the treatment of androgenetic alopecia for CU-40102 in China and we have commenced pilot commercialization of CU-40102 in Lecheng, Hainan. We expect to complete the primary endpoint read-out for the Phase III clinical trial in the fourth quarter in 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in the fourth quarter of 2024.
- *CU-40101.* We are currently conducting a Phase I clinical trial for CU-40101. We expect to complete the Phase I clinical trial in the second quarter of 2024.

- *CU-40103.* We are currently conducting the pre-clinical study of CU-40103. We plan to submit an ANDA to the NMPA in the third quarter of 2024.
- *CU-40104*. We are currently conducting the pre-clinical study of CU-40104. We plan to submit an IND application to the NMPA in the fourth quarter of 2024.

# Skin Diseases and Care

- *Key Product CU-10201.* We are currently conducting a Phase III clinical trial for CU-10201, and we have commenced pilot commercialization of CU-10201 in Lecheng, Hainan. We expect to complete the primary endpoint read-out for the Phase III clinical trial in the first quarter of 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in the fourth quarter of 2024.
- *CU-10101*. We are currently under the pre-clinical stage for CU-10101. We plan to submit an IND application to the NMPA in the second quarter of 2024.
- *CU-10401.* We are currently conducting the pre-clinical study of CU-10401. We plan to submit an ANDA to the NMPA in 2026.

# Topical Anesthesia

• *CU-30101*. We received the NMPA's IND approval for CU-30101 in November 2022. We plan to commence the Phase III clinical trial in the second quarter of 2023 and submit an NDA to the NMPA in 2025.

# Expand Our Ecosystem Coverage and Build Our Commercialization Team

We will continue to expand our ecosystem coverage. Our future collaboration efforts will include:

- Industry-academia research collaboration with medical institutions and PIs. This allows us to access advanced medical technologies, deepen our understandings of dermatology and obtain latest feedbacks from clinical practices. By working with healthcare professionals such as leading PIs, we believe we will be able to educate market participants, cultivate dermatology management habits among patients, and promote our brand.
- *OEM/ODM collaborations with upstream players of industry supply chain.* This enhances our manufacturing capabilities, strengthens our supply chain management capabilities and shortens our R&D, clinical development and commercialization processes.

- *Co-development and co-marketing with other downstream medical and commercial institutions.* We plan to continue penetrating the downstream of the healthcare value chain. This enables us to further expand our product pipeline and optimize the allocation of our R&D and commercialization resources.
- *Collaborations with e-commerce platforms.* This enables us to efficiently reach a wide range of potential customers as well as collect and analyze their first-hand feedbacks, which facilitates our efforts to identify and address market demands through targeted product development.

Our integrated commercialization model is expected to address the pain points of the traditional commercialization model, such as fierce traffic competition, high customer acquisition costs and uncertain profitability. By seizing the opportunities arising from the rapid expansion of China's sales network, we endeavor to innovate omni-channel commercialization models for pharmaceutical sales to drive our market share, and develop standardized operations with high scalability, setting a significant industry barrier. On one hand, we intend to make content platforms to formulate targeted marketing strategies for our products and conduct online and offline promotion events and activities. On the other hand, with established brand recognition and relationships with medical institutions, we plan to establish strategic cooperative relationships with Class III Grade A hospitals in China. In terms of our commercialization coverage, we plan to focus on promoting to around 20 Class III Grade A hospitals in China in the first year after CU-20401's approval. We intend to build up collaborative relationships with these hospitals through CU-20401's Phase III clinical trial. We also plan to adopt a tiered provincial market-entry approach with the goal of achieving nationwide coverage in the medium term. Our priority is to initially focus on top tier provinces that have high patient orcustomer volume capture. As we expand into tier two and lower tier provinces, we plan to continue to invest in building our on-the-ground presence and coverage. We will seek to strengthen our relationships with key stakeholders in each province to drive diagnosis and treatment, and also to support reimbursement negotiation into provincial formulary. We believe these marketing and business development strategies will help us obtain market shares in the indications that we focus on. We will also continue to expand our commercialization team which integrates our medical, business development and marketing teams with online and offline commercial capabilities.

Our marketing team is in charge of our online and offline promotions and aims to build long-term relationships with medical institutions, healthcare professionals and KOLs through academic conferences, seminars and on-site medical trainings. By doing so, we expect to educate physicians the safety and efficacy of our products, which could in turn improve the awareness of our products among our target customers. Our business development team will be responsible for expanding our commercialization ecosystem coverage and collaboration network, which could strongly empower our commercialization capabilities.

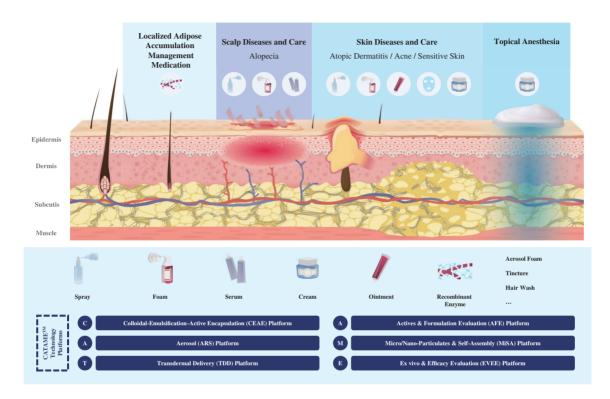
#### **Expand Our Presence**

We are committed to becoming a dermatology platform and improving the quality of life for patients worldwide. We plan to expand into countries and regions with considerable market potential for dermatology solutions based on our resources and commercial readiness. We are well prepared to mitigate the risks of market concentration by adopting differentiated pricing policies across different regions. We aim to establish overseas offices and operate local teams where appropriate, in order to fulfill local responsibilities including business development, conducting clinical trials, registration and commercialization.

Complementing our organic growth strategy, we aim to fuel our business growth through establishing strategic alliances with partners and pursuing investments and acquisitions with synergistic businesses. When selecting potential acquisition, investment or in-licensing arrangement targets, we will consider various criteria, including (i) synergy with or complement to its business operations, (ii) R&D capabilities in dermatology products, (iii) geographic locations, (iv) growth potential, and (v) financial performance or projections. We became acquainted with our corresponding collaborating counterparties through our management team's industry network or business development. In the future, we will seek acquisition or cooperation opportunities with companies with alternative dermatological technologies to enrich our offerings to customers. We also intend to collaborate and transfer our leading technologies to organizations who aspire to implement and utilize these technologies to expedite the drug innovation process and lower production costs.

#### **PRODUCT CANDIDATES**

Our broad portfolio targets the four main sectors of the broader dermatology treatment and care market, namely localized adipose accumulation management medication, scalp diseases and care, skin diseases and care and topical anesthesia. The following image illustrates the four main segments of the broader dermatology treatment and care market and the application of our products to the respective skin conditions.



Source: Frost & Sullivan analysis

As of the Latest Practicable Date, we had built a broad portfolio of nine products and product candidates. We are developing five clinical-stage and four pre-clinical stage drug candidates. Among the five clinical-stage drug candidates, two products have commenced pilot commercialization in Lecheng, Hainan. We also distributed two commercialized products developed by overseas collaboration partners. The following chart summarizes the development status of our distributed products, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the Latest Practicable Date:

Therapeutic Areas	Candidate	Active Ingredients & Formulation		OTC / Prescription Drugs	Commercial Rights	Source	Pre- Clinical	IND Phase I	e I Phase II	II Phase III	Registration	ion Commercialization		Upcoming Milestone	Expected Commercial Launch	NMPA Registration Classification <sup>10</sup>
		t mutant	Submental Adipose Accumulation (Submental Fat)	Prescription drug	e e e	Aconirad	_	_					Initiat 3Q205	Initiate Phase II in 3Q2023	2028	-
Accumulation Management	CU-20401-	CU-20401- collagenase	Abdominal Adipose Accumulation (Abdominal Fat)	0	A SN A								Comp 2024	Complete Phase I in 2024	2028	
	CU-40102 <sup>3</sup>	CU-40102 <sup>3</sup> M Topical finasteride spray	٩,	Prescription drug	Greater China <sup>9</sup> In-licensed	In-licensed							NDA NMP	NDA submission to NMPA in 4Q2023	4Q2024	5.1
Scalp Disease and Care	CU-401014	Topical small molecule thyroid hormone receptor agonist liniment	Alopecia	Prescription drug	Asia	In-licensed							Complet 2Q2024	Complete Phase I in 2Q2024	TBD	Т
	CU-40103	Topical minoxidil foam	Alopecia	OTC	Global	Self- developed							AND/ to NM	ANDA submission to NMPA in 3Q2024	2025	3
	CU-40104	Topical dutasteride agent Androgenic Alopecia	t Androgenic Alopecia	Prescription drug	Global	Self- developed							IND a submi NMP/	IND application submission to NMPA in 4Q2024	TBD	0
	CU-102015	Topical 4% minocycline Acne Vulgaris foam	Acne Vulgaris	Prescription drug	Greater China <sup>9</sup> In-licensed	In-licensed							NDA NMP/	NDA submission to NMPA in 4Q2023	4Q2024	5.1
Skin Disease and Care	CU-101016	Topical novel small molecule agent	Atopic Dermatitis	Prescription drug	Greater China°, Japan, South Korea and SEA	In-licensed							IND a submi NMP/	IND application submission to NMPA in 2Q2024	TBD	_
	CU-104017	Topical tapinarof cream	Psoriasis	Prescription drug	Greater China <sup>9</sup> , Japan, South Korea and SEA	Acquired							AND, to NM	ANDA submission to NMPA in 2026	2027	4
Topical Anesthesia	CU-30101 <sup>8</sup>	Localized topical lidocaine and tetracaine cream	Surface Dermatologic Operations	Prescription drug	Greater China <sup>9</sup>	Acquired			_				Commence in 2Q2023	Commence Phase III in 2Q2023	2026	n
Core	★ Denotes Core Product 🛛 📕	Denotes Key Products	N Denotes prod	M Denotes products in registrational trials in China with pilot commercialization in Lecheng, Hainan	trials in China w	ith pilot comn	<i>ercialization</i>	n in Lecheng	g, Hainan							

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# **BUSINESS**

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**BUSINESS** 

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#### LOCALIZED ADIPOSE ACCUMULATION MANAGEMENT MEDICATION

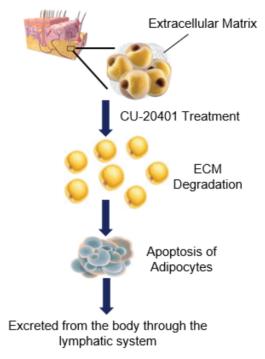
#### Core Product CU-20401: A Recombinant Mutant Collagenase

#### Overview

CU-20401 is a 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. 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 significantly 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 the asset transfer of CU-20401. The formulation of CU-20401 includes recombinant mutant collagenase, trometamol, sucrose, calcium chloride, hydrochloric acid and water. We have completed Phase I clinical trial of CU-20401 on human subjects for submental adipose accumulation (submental fat) and are conducting another Phase I clinical trial for abdominal adipose accumulation (abdominal 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 the Phase II clinical trial of CU-20401 for submental adipose accumulation (submental fat) in the third quarter of 2023.

#### Mechanism of Action

Collagenases are enzymes that break the peptide bonds in collagen. Collagenase exists in various human tissues, including uterus, bones and wound-healing tissues, and can hydrolyze the peptide bonds in collagen. Human fat tissue mainly consists of adipocytes that are surrounded by and attached to the extracellular matrix mainly composed of collagen network. Once the collagen network is degraded by the collagenase, the fat cells are detached and isolated, losing the mechanical and physiological support by the extracellular matrix and consequently undergoing apoptosis. Local adipose tissue volume can hence be reduced in the area where the collagenase is administrated. CU-20401 is a recombinant mutant collagenase, with the glutamate on amino acid site 451 of wild-type collagenase mutated to aspartate (E451D). The E451D mutation does not affect the affinity of the collagenase to bind the substrate, but significantly reduces the rate to catalyze the breakdown of collagen. After subcutaneous administration, CU-20401 acts on and degrades the collagen in the targeted area, dispersing the aggregated adjpocytes and leading to loss of support from the extracellular matrix and finally apoptosis, improving the skin laxity appearance. The enzymatic degradation of collagen by CU-20401 is relatively mild compared to wild-type collagenase, potentially reducing the adverse effects of wild-type collagenase such as bruising and pain.



The diagram below illustrates the mechanism of action of CU-20401:

Source: Frost & Sullivan analysis

#### Market Opportunity and Competition

Current treatment for localized adipose accumulation includes, among others, energybased fat reduction procedures. No localized adipose accumulation management medication product has been approved in China. The localized adipose accumulation management medication products' ingredients dissolve local fat and facilitate local fat metabolism, which is suitable for individuals who seek effective solutions to local fat accumulation that is not fully addressed by exercise and diet.

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 grow continuously, (iv) customers 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.

According to Frost & Sullivan, there are currently no approved localized adipose accumulation management medication products in China. We believe that CU-20401 is well-positioned to capture the growth of the localized adipose accumulation management medication market in China for labelled use, which is expected to reach RMB2,439.9 million in 2030, according to the same source.

#### Summary of Clinical Trial Results

We designed two separate clinical trials for CU-20401 targeting submental adipose accumulation (submental fat) and abdominal adipose accumulation (abdominal fat), respectively. We present the results of the clinical trials below.

# Phase I Clinical Trial of CU-20401 for Submental Adipose Accumulation (Submental Fat) Sponsored by us

Overview. The Phase I clinical trial is a single-center, non-randomized, single-arm, dose study to evaluate the safety, PK characteristics, preliminary efficacy and immunogenicity of CU-20401 in different groups of adult subjects with excessive submental adipose accumulation aged between 18 to 65 years old in China. The primary endpoint of the Phase I clinical trial is to evaluate the safety of CU-20401 in the submental adipose accumulation subjects. The secondary endpoint of the Phase I clinical trial is to evaluate the pharmacokinetic profile, preliminary efficacy and immunogenicity of CU-20401 in the submental adipose accumulation subjects. The primary endpoint of the Phase I clinical trial had been reached, suggesting that CU-20401 is safe and well tolerated in subjects with submental adipose accumulation. The Phase I clinical trial also has demonstrated preliminary efficacy of CU-20401 and the recommended Phase II dose (RP2D) of CU-20401 should be 0.06mg/dose or 0.08mg/dose for the subsequent Phase II clinical trial in China.

<u>Trial design.</u> The Phase I clinical trial enrolled 49 subjects in total, 48 subjects received treatments and were divided into six cohorts (A1, A2, B1, B2, C1, C2) with eight subjects in each cohort. The cohorts would be treated with CU-20401, with a dosage design as set forth below. Safety evaluation indications included: vital signs, 12-lead electrocardiogram, clinical laboratory test indicators, physical examination, local skin reactions, and other adverse events. Efficacy evaluation indicators included: (i) clinician-reported submental fat rating scale (CR-SMFRS) to assess the proportion of subjects with submental fat (SMF) Grade  $\leq 1$ , (ii) submental skin relaxation scale (SLRS) to assess the change in SMF skin laxity from baseline, (iii) patient-reported submental fat rating scale (PR-SMFRS) to assess the change in SMF from baseline, (iv) subject self-rating scale (SSRS) to assess the proportion of subjects with at least 10% reduction in submental fat area from baseline, and (vi) global aesthetic improvement scale to assess changes from baseline. The efficacy is observed using both subjective scores, such as CR-SMFRS and PR-SMFRS, as well as objective evaluations, such as magnetic resonance angiography.

Cohorts	<b>Formulation</b> (mg)	Dose (ml)	<b>Concentration</b> <b>per dose</b> (mg/ml)	Number of doses	Total dose (mg)
A1	0.02	0.2	0.1	2	0.04
A2	0.04	0.2	0.2	2	0.08
<b>B1</b>	0.04	0.2	0.2	4	0.16
B2	0.06	0.2	0.3	4	0.24
C1	0.06	0.2	0.3	6	0.36
C2	0.08	0.2	0.4	6	0.48

<u>Trial status.</u> We initiated the Phase I clinical trial in February 2022 and completed the trial in November 2022.

Safety data. The most commonly reported treatment emergent adverse events (TEAEs) included edema, pain, tenderness, bruising and swelling, and erythema. The majority of subjects (43/48) had a Grade 1 TEAE related to CU-20401 and a few subjects (4/48) had a Grade 2 TEAE. Only one subject had a sub-Grade 3 TEAE related to CU-20401, namely reduced neutrophil count. The subject with the sub-Grade 3 TEAE enrolled in the lowest dose cohort was recovered without any intervention. Considering that most of the subjects (47/48) did not have such sub-Grade 3 TEAE, the possible reason for the subject with the sub-Grade 3 TEAE may be an incidental event that the subject had specific individual features. The CU-20401 is the recombinant collagenase with the E451D mutation to treat submental adipose accumulation, with no potential effects regarding proliferation and differentiation of neutrophil and count thereof. As such, in light of the mechanism of CU-20401 and the whole clinical trial that most of the subjects did not have reduced neutrophil count, CU-20401 showed no off-target effects on reduction of neutrophil count. All subjects had no serious adverse events, no TEAEs leading to withdrawal from the clinical trial, and no TEAEs leading to death, suggesting a good safety and tolerability profile for CU-20401.

Efficacy data. At day 28 (D28) after CU-20401 treatment, the efficacy profiles among six cohorts A1, A2, B1, B2, C1, and C2 are set forth below. (i) CR-SMFRS is a rating scale system reported by clinicians to evaluate the degree of submental fat level accumulation. The lower the scale, the less the accumulation. The proportion of subjects with 1-scale decrease in CR-SMFRS was 62.5%, 37.5%, 50.0%, 75.0%, 50.0%, and 37.5%, respectively. Because lower scale of CR-SMFRS indicates less accumulation, after CU-20401 treatment, patients with 1-scale decrease suggest that the CU-20401 treatment is able to decrease submental fat accumulation evaluated by clinicians. (ii) PR-SMFRS is a similar rating scale system reported by patients. The mean decrease from baseline in PR-SMFRS was  $0.5\pm0.76$ ,  $0.8\pm0.71$ ,  $1.3\pm0.71$ ,  $0.8\pm0.71$ ,  $1.0\pm0.53$ , and  $0.6\pm0.74$  points, respectively. Similar to CR-SMFRS, lower scale indicates less fat accumulation. After CU-20401 treatment, the scale is decreased from the baseline, suggesting the preliminary efficacy for CU-20401 treatment assessed by patients. (iii) SLRS is a scale system evaluated by physicians to reflect submental skin relaxation. The mean decrease from baseline in SLRS was  $0.1\pm0.35$ ,  $0.1\pm0.35$ ,  $0.6\pm0.52$ ,  $0.6\pm0.52$ , and  $0.3\pm0.46$  points, respectively. SLRS uses lower scale to indicate less relaxation. CU-20401

treatment decreased the patients' scale from baseline, suggesting the preliminary efficacy for CU-20401 to ameliorate skin relaxation. (iv) SSRS is an SMF score system to reflect the patient satisfaction with their face and chin. The percentage of subjects with submental fat scores  $\geq 3$  points were 50.0%, 75.0%, 50.0%, 50.0%, 50.0%, and 37.5%, respectively. The high percentage in the SSRS system demonstrates the patients' satisfaction for CU-20401 treatment. (v) The proportion of subjects with at least 10% reduction in submental fat area from baseline (i.e.,  $\geq 10\%$  reduction) by magnetic resonance angiography were 0, 12.5%, 37.5%, 25.0%, 25.0%, and 12.5%, respectively. The percentage of subjects after CU-20401 treatment suggests the efficacy of CU-20401 to decrease submental fat area. (vi) 66.7% of subjects perceived an improvement over the initial status at D28 or when exited early based on the global aesthetic improvement scale system. In conclusion, CU-20401 demonstrated preliminary efficacy in the submental adipose accumulation population.

Cohorts	CR-SMFRS 1-scale decrease	PR-SMFRS decreased from baseline	SLRS decreased from baseline	SMF Score≥3	Proportion of subjects with at least 10% reduction in SMF from baseline
A1	62.5%	$0.5 \pm 0.76$	0.1±0.35	50.0%	0
A2	37.5%	$0.8 \pm 0.71$	0.1±0.35	75.0%	12.5%
B1	50.0%	1.3±0.71	0.1±0.35	50.0%	37.5%
B2	75.0%	$0.8 \pm 0.71$	$0.6 \pm 0.52$	50.0%	25.0%
C1	50.0%	1.0±0.53	$0.6 \pm 0.52$	50.0%	25.0%
C2	37.5%	$0.6 \pm 0.74$	$0.3 \pm 0.46$	37.5%	12.5%

Source: Company data (clinical study report)

Phase I Clinical Trial of CU-20401 for Abdominal Adipose Accumulation (Abdominal Fat) Sponsored by us

Overview. This was a single-center, open label, placebo-controlled, dose escalation Phase I clinical trial in healthy subjects aged between 21 to 50 years old in China. The primary objective was to assess the safety and tolerance of CU-20401 single-dose administration in healthy subjects. The primary objective for this clinical trial is to observe the safety and tolerability of CU-20401, and the secondary objectives include pharmacokinetics, efficacy and immunogenicity. The Phase I clinical trial is a single-dose escalation study with eight dose cohorts of six subjects for each cohort. Our Phase I clinical trial for abdominal adipose accumulation substantially differs from Rejuven's Phase I clinical trial for abdominal fat in the U.S. for the following reasons: (i) our Phase I clinical trial has more designed safety indicators; (ii) our Phase I clinical trial observes pharmacokinetics and immunogenicity, both of which are absent in the Rejuven study; (iii) our Phase I clinical trial determines the efficacy endpoint by ultrasound and magnetic resonance imaging, while the Rejuven study determines the efficacy

endpoint by ultrasound only; and (iv) our follow-up observation period is extended to three months. After we obtained IND approval from the NMPA, we initiated the trial in December 2021 and the trial design was subject to adjustment to confirm the RP2D. We plan to enroll 48 patients and complete the Phase I clinical trial in 2024. As of the Latest Practicable Date, this trial was still actively recruiting subjects with 18 patients enrolled, and no preliminary clinical result was available for analysis.

#### Asset Transfer and Joint Collaboration

On August 28, 2020, we entered into an agreement (the "**CU-20401 Agreement**") with Rejuven Dermaceutical Co., Ltd., ("**Rejuven**"). 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 and we have exclusive rights to develop, manufacture and commercialize CU-20401 in Asia for existing and future expanded indications, including adipose accumulation management and other indications such as cellulite repair and scar modification. We also formed joint collaboration with Rejuven in relation to clinical development in Asia. For more details, see "– Collaboration and Licensing Arrangements – CU-20401 Agreement."

Pursuant to the CU-20401 Agreement, Rejuven transfers the interests of CU-20401 in Asia to us, because (i) Rejuven plans to find a long-term collaborator for developing and commercializing CU-20401 in Asia so that Rejuven could focus on its development in other countries, such as the U.S.; (ii) as an R&D-driven, dermatology-focused biopharmaceutical company, we have developed and are still developing our pipeline product candidates covering broad dermatology products and our CATAME<sup>®</sup> platform with strong R&D capabilities; and (iii) this long-term collaboration integrates strengths and resources from both Rejuven and us, thus facilitating the development and commercialization of CU-20401. Upon expiration or termination of the Agreement, the Joint Collaboration will be terminated while the Asset Transfer will remain to be effective.

As of the Latest Practicable Date, we had not expanded CU-20401 into future indications other than the indication currently being developed. In addition to China, we have other counties or regions in Asia that we have right but has not started developing CU-20401. According to the CU-20401 Agreement, we can expand our indication in China without need to obtain further consent or reach additional amendments of the current agreement with Rejuven. The current development and commercial milestone payment, royalty payment, termination arrangement and Joint Collaboration under the CU-20401 Agreement also cover future indication expansions. The CU-20401 Agreement does not impose additional obligation on us in case of adverse effect during the development in the expanded indication or geographic area.

#### **Clinical Development Plan**

We completed the Phase I clinical trial of CU-20401 for the treatment of submental adipose accumulation in November 2022 and are conducting another Phase I clinical trial for abdominal adipose accumulation. 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 the Phase II clinical trial of CU-20401 for submental adipose accumulation in the third quarter of 2023. The Phase II clinical trial is a multi-center, randomized, placebo-parallel controlled clinical trial. The primary objective of the Phase II clinical trial is to assess the efficacy of CU-20401 in subjects with submental adipose accumulation. The secondary objective of the Phase II clinical trial is the assessment of safety and immunogenicity of CU-20401 in subjects with submental adipose accumulation. The Phase II clinical trial plans to enroll 120 subjects, divided into three treatment cohorts and one control cohort, with 30 subjects in each cohort. We expect to complete the Phase II clinical trial of CU-20401 for submental adipose accumulation in 2025, and initiate a Phase III clinical trial for submental adipose accumulation in 2025. 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. We have obtained the NMPA approval for the clinical trials and we, as the sponsor, have initiated a Phase I clinical trial for abdominal adipose accumulation and completed a Phase I clinical trial for submental adipose accumulation. Therefore, we believe CU-20401's future potential trials in the U.S. sponsored by Rejuven do not impact NMPA's review of CU-20401 in China.

#### Our R&D Work since Acquisition and Material Communications with Competent Authorities

Prior to our acquisition of CU-20401 from Rejuven, Rejuven had conducted several pre-clinical studies of CU-20401 but had not formulated or filed any clinical trial plans in Asia for CU-20401. We commenced our R&D efforts of CU-20401 around December 2020. Since then, we have made R&D progress on CU-20401 including, among others, the analysis of CU-20401 to identify the variances between regulatory standards and current R&D progress, covering analysis from pre-clinical, CMC and clinical perspectives.

We received IND approval from the NMPA for the Phase I clinical trial to assess the safety and tolerance of CU-20401 in August 2021. We completed the study for the Phase I clinical trial for submental adipose accumulation in November 2022. Our Phase I clinical trial results for submental adipose accumulation showed favorable safety profile and that the RP2D of CU-20401 should be 0.06mg/dose or 0.08mg/dose for the subsequent Phase II clinical trial in China. We expect to commence Phase II clinical trial in or around July 2023. We are also actively recruiting patients for a Phase I clinical trial of CU-20401 for abdominal adipose accumulation. Our major milestones of R&D work and material communication with competent authorities for CU-20401 since acquisition include the following:

• *Pre-clinical studies and CMC:* We have cooperated with CROs and CDMOs to conduct more than 20 pre-clinical studies and develop CMC for CU-20401. The patent was originally granted in May 2020 with the patent owner of Rejuven. Pursuant to the CU-20401 Agreement, Rejuven transferred the patent ownership to us in October 2020.

- *Pre-IND communication:* Since December 2020, we had a series of pre-IND meetings with the NMPA during which we discussed the pre-clinical results and clinical development plan of CU-20401 in China.
- *Phase I clinical trial design:* Our R&D team commenced the clinical trial design of a Phase I clinical study of safety, tolerability, and pharmacokinetics of CU-20401 in healthy subjects in China in April 2021. The clinical trial design was finalized in the same month.
- Submission of IND application to the NMPA: In May 2021, we, as the sole sponsor, submitted to the NMPA the IND application for a Phase I clinical study of safety, tolerability, and pharmacokinetics of CU-20401 in healthy subjects in China.
- *Phase I approval of IND application from the NMPA:* In August 2021, we received IND approval for the aforementioned Phase I clinical trial of CU-20401. In the approval letter, as CU-20401 is indicated for submental adipose accumulation and the proposed Phase I clinical trial is designed as subcutaneous abdominal administration in healthy subjects, the NMPA recommended an additional submental administration study of CU-20401 to assess its PK and safety profile.
- Consultation with CDE regarding Phase I and Phase II clinical trial of CU-20401 for submental adipose accumulation: In August 2021, based on the NMPA's recommendation in the IND approval letter, we consulted the CDE as to whether another Phase I and Phase II clinical trial of CU-20401 for the treatment of submental adipose accumulation could be initiated directly without filing an IND with NMPA. We will submit a meeting request to the CDE before initiation of Phase III clinical trial after the end of Phase II clinical trial. In September 2021, the CDE confirmed additional IND application was not needed if we obtained ethics committee (the "EC") approval and submitted the Phase I and Phase II clinical trial design on the CDE website.
- *Phase I and Phase II clinical trial design:* Based on the NMPA's recommendation, we have formulated a Phase I and Phase II clinical trial design of CU-20401 for submental adipose accumulation.
- Submission of EC application for a Phase I and Phase II clinical trial: In September 2021, we filed a submission to the EC in relation to our Phase I and Phase II clinical trial design for submental adipose accumulation in China.
- *EC approval for Phase I and Phase II clinical trial*: In October 2021, we received EC approval for the Phase I and Phase II clinical trial of CU-20401 for submental adipose accumulation.

- Submission of Phase I and Phase II trial design on the CDE website: In November 2021, we submitted the Phase I and Phase II clinical trial design of CU-20401 for submental adipose accumulation on the CDE website. After the CDE's review, the Phase I and Phase II clinical trial designs were approved and registered on the CDE website in December 2021.
- *Key preparation for clinical trials:* We communicate with Rejuven regarding the sharing of clinical trial data and progress and maintain extensive collaboration with Rejuven for CU-20401. In addition, under the CU-20401 Agreement, we have exclusive rights to develop, manufacture and commercialize CU-20401 in Asia for potential indications, including but not limited to adipose accumulation management and other indications such as cellulite repair and scar modification. We will notify Rejuven if we plan to expand indications to other indication. Our medical team continued to actively collaborate with CROs in the Phase I clinical trial of CU-20401 to (i) analyze data on clinical needs; (ii) develop and validate PK analysis methodology; (iii) finalize the statistical analysis plan, risk management plan, medical monitoring plan and data management plan; (iv) conduct site selection; (v) apply for EC approval; (vi) prepare several clinical trials; and (vii) conduct meetings with principal investigators for the Phase I clinical trial.

As advised by our PRC Legal Advisor, the CDE is responsible for evaluating drug clinical trial applications, drug marketing authorization applications, supplementary applications, and overseas production drug re-registration applications. It is the competent authority with regulatory responsibility for the IND application and its approval of CU-20401.

The original protocol communicated with the CDE covers both Phase I and Phase II clinical trials of CU-20401, and Phase I and Phase II clinical trials are two separate trials with different endpoints. On January 13, 2023, our PRC Legal Advisor consulted the CDE regarding the commencement of a Phase II clinical trial after the completion of the Phase I clinical trial. According to the CDE, (i) the NMPA is not responsible for either certifying or providing assurance for the completion of any clinical trials and the NMPA will not confirm the completion of a Phase I clinical trial before initiation of the Phase II clinical trial, and (ii) for Phase I and Phase II clinical trials for new drugs, the NMPA has optimized its review and approval procedure and accordingly adopts one-time approvals instead of phased declarations, reviews and approvals. Therefore, a company does not have to obtain additional approval or confirmation from the NMPA for commencing the Phase II after it completes the Phase I if that company has obtained an umbrella IND approval to carry out both Phase I and Phase II clinical trial and approval to carry out both Phase I and Phase II clinical trial without any pre-requisite conditions imposed. Therefore, as advised by our PRC Legal Advisor, there is no legal impediment to initiate the Phase II clinical trial.

Furthermore, the sponsor and the principal investigator have the discretion to determine whether the Phase I clinical trial has reached its primary endpoints and whether to initiate the Phase II clinical trial, and the principal investigator and the Company discussed the data from the Phase I clinical trial in the finalized clinical study report and determined that the primary

endpoint for the Phase I on submental adipose accumulation had been met. Since the primary endpoints of the Phase I clinical trial were reached, no additional approval or confirmation for the Phase II clinical trial from the NMPA is required because the RP2D selected did not exceed the highest dose in the protocol originally approved by the NMPA. We, as the sponsor of the Phase I and Phase II clinical trial of CU-20401 for submental adipose accumulation, confirm that the design of the Phase II clinical trial will follow the original protocol without any material modifications, and that the first patient is expected to be dosed in July 2023. We need to conduct substantial preparation work before initiating the Phase II trial, including but not limited to recruiting patients, selecting clinical sites and engaging CROs and CDMOs, among other clinical service providers where necessary. According to Frost & Sullivan, a six-month preparation period before first-patient-in of a Phase II clinical trial is not uncommon and is in line with market practice. Therefore, the NMPA has no objection for us to commence the Phase II clinical trial of CU-20401 for submental adipose accumulation.

According to the NMPA's IND approvals and as advised by our PRC Legal Advisor, the proposed indications of submental adipose accumulation and abdominal adipose accumulation for CU-20401 are regulated as one single product, and submental adipose accumulation and abdominal adipose accumulation are two indications that require separate research capabilities and development programs.

We received IND approval from the NMPA for the Phase I clinical trial to assess the safety and tolerance of CU-20401 in treating abdominal adipose accumulation in August 2021.

We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-20401 SUCCESSFULLY.

#### SCALP DISEASES AND CARE

Androgenetic alopecia is a common form of scalp disease that affects both men and women. It is characterized by progressive hair loss. Currently medication for androgenetic alopecia include minoxidil, finasteride and cyproterone. Minoxidil and finasteride are both commonly used in the treatment of androgenetic alopecia and they can be used in combination. Over 70% androgenetic alopecia patients were treated with minoxidil or finasteride in 2021 in the U.S. and China, according to Frost & Sullivan. Adverse events arising from minoxidil products include allergy to propylene glycol and orthostatic hypotension. Finasteride is only available in oral form in China with potential significant adverse effects and cannot be used by female patients. Patients using finasteride may experience sexual adverse effects such as decreased libido, erectile dysfunction and ejaculation disorder, of which incidence rates were 1.8%, 1.3% and 1.2% in clinical trials, respectively. Cyproterone can only be used in female patients. As current therapies have higher risks of severe adverse effects, new therapies under development with fewer adverse effects are expected to seize great market opportunities. We

believe that our scalp disease products are well positioned to address the unmet needs and capture the growing market of scalp diseases and care products in China. It is estimated that the market will increase from RMB106.9 billion in 2021 to RMB144.3 billion in 2025, representing a CAGR of 7.8%, and further increase to RMB203.5 billion in 2030, representing a CAGR of 7.1% from 2025 to 2030. We have formed a comprehensive pipeline comprised of four products and product candidates for scalp diseases and care, including CU-40102 (topical finasteride spray), CU-40103 (topical minoxidil foam), CU-40101 (topical small molecule hormone receptor agonist liniment), CU-40104 (topical dutasteride agent), and two distributed products CUP-MNDE (topical minoxidil spray) and CUP-SFJH (topical natural plant extracts).

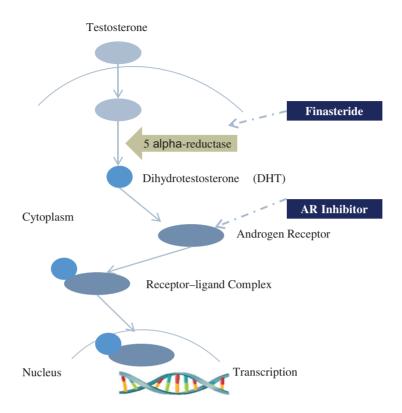
#### Key Product CU-40102: Phase III Clinical-Stage Topical Finasteride Spray

#### Overview

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. The global annual sales of finasteride products for the treatment of alopecia increased from US\$320.3 million in 2017 to US\$348.1 million in 2021, representing a CAGR of 2.1%, according to Frost & Sullivan. Growing prevalence of androgenetic alopecia in China presents enormous market potential for scalp disease treatment and subsequent scalp care maintenance. CU-40102's topical finasteride formulation is applied by spraying onto the scalp. We are currently conducting a Phase I clinical trial for PK and a registrational Phase III clinical trial for CU-40102 in Mainland China, and we have commenced pilot commercialization of CU-40102 in Lecheng, Hainan. We expect to complete the primary endpoint read-out for the Phase III clinical trial in the fourth quarter of 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in the fourth guarter of 2024.

#### Mechanism of Action

Androgenetic alopecia is a scalp disease in which androgens cause hair follicle miniaturization which in turn results in hair shaft thinning and hair loss. Testosterone is the major circulating androgen and can be converted to the more potent androgen, DHT, by 5-alpha reductases. In the scalp of men with androgenetic alopecia, the rate of conversion of testosterone to DHT is accelerated in the balding region compared to the unaffected region. Finasteride, as a specific inhibitor for 5 alpha-reductase, suppresses the conversion of testosterone to DHT in the scalp and further blocks the interaction of DHT and androgen receptor, thereby decreasing the transcription control of androgen-dependent genes to delay the progression of androgenetic alopecia.



The diagram below illustrates the mechanism of action of CU-40102:

Source: Frost & Sullivan analysis

#### **Competitive** Advantages

We believe that CU-40102 has the following advantages:

#### High Concentrations of Finasteride on the Scalp Surface

CU-40102 is a formulation of 2.275 mg/ml finasteride (corresponding to 0.25% concentration) using a hydrolacquers technology that is based on a hydroalcoholic solution of hydroxypropyl chitosan, a water-soluble synthetic derivative of chitosan. The hydroalcoholic solution of hydroxypropyl chitosan acts as a structure-providing agent, with a good safety profile including biological inertness, non-toxicity, non-irritation and non-potential allergenicity. The CU-40102 topical formulation is a finasteride spray in a vial with a spray pump, which makes distribution of the finasteride spray by a measurable and controllable amount easily and evenly on the scalp. After administration to the scalp, the solvent evaporates rapidly and hydroxypropyl chitosan forms a smooth, water-soluble, transparent, matt and almost invisible structural layer containing the active ingredient finasteride. This structural layer maintains a high concentration of finasteride on the surface of the scalp for sufficient time to allow the finasteride to penetrate skin layers and reach the reticular layers where most of the follicle bulbs are located.

#### Low Systemic Drug Exposure and Toxicity

As a topical formulation, CU-40102 reduces systemic absorption of finasteride and avoids exposure of other areas of the skin to finasteride. Both the Phase IIa in Switzerland and the Phase III multi-regional clinical trials in male patients with androgenetic alopecia sponsored by Polichem S.A. showed that only very low concentrations of finasteride were detected in plasma after CU-40102 administration and no significant absorption was observed. In the Phase III clinical trial in male patients with androgenetic alopecia to evaluate safety and efficacy of topical finasteride compared with oral finasteride sponsored by Polichem S.A., average maximum finasteride plasma concentrations following the proposed dose (i.e., up to 200 µL once a day) of CU-40102 administration were more than 100-fold lower than oral finasteride administration ( $\leq$ 48.0 pg/mL vs. 7166 pg/mL) at all sampling time points during the 24-week treatment period. Similarly, the average percentage reduction in serum DHT of CU-40102 administration was also less than that of oral finasteride at all sampling time points during the treatment period, and the average percentage reduction in serum DHT at week 24 was 34.5% in the CU-40102 group compared with 55.6% in the oral finasteride group, suggesting much lower systemic inhibition of 5 alpha-reductase by CU-40102 topical administration than that of oral finasteride treatment. CU-40102 topical formulation, as compared with oral finasteride, can reduce the serum DHT suppression with statistical significance and reduces the incidence of systemic adverse effects without statistical tests.

#### Commercial Prospect

Finasteride as an existing compound has been well trusted by physicians and widely accepted by the market. Polichem S.A. first obtained market approval in German for CU-40102 with the brand name of Finjuve<sup>®</sup>. The global annual sales of finasteride products for the treatment of alopecia reached US\$348.1 million in 2021, according to Frost & Sullivan. The current oral formulation of finasteride is a typical treatment for androgenetic alopecia but with a higher risk of causing side effects than the topical drug due to higher drug exposure. CU-40102's topical finasteride formulation is applied by spraying onto the scalp. CU-40102 accordingly is expected to fill in the unmet demand gap to reduce side effects in consumer group where there is currently no topically used finasteride approved. In addition, CU-40102 is the only topical finasteride under development in China and has been approved for sale in a pilot program in Lecheng, Hainan. Thus, we believe CU-40102 would potentially be the first and only topical finasteride in China by the expected time of its approval and will capture meaningful market shares.

#### Summary of Clinical Trial Results

The clinical pharmacology, efficacy and safety of CU-40102 have been elucidated through a clinical development program consisting of six completed clinical trials. Among these trials, CU-40102 was generally well-tolerated and showed evidence of efficacy. We present the results of key clinical trials below.

Phase III Clinical Trial of CU-40102 in Male Patients with Androgenetic Alopecia Sponsored by Polichem S.A.

<u>Overview.</u> This was a registrational multi-center, double-blind, randomized, parallelgroup, placebo and active-controlled Phase III clinical trial to evaluate the efficacy and safety of CU-40102 topical spray solution in male androgenetic alopecia patients. The primary objective of the clinical trial was to determine whether topical administration of CU-40102 once a day to the scalp of patients with androgenetic alopecia for up to 24 weeks increases hair count compared to the excipient. All primary endpoints were met.

<u>Trial Design.</u> Male patients aged between 18 to 40 years were divided into three groups for treatment: (1) CU-40102 group (181 patients): up to 4 sprays (i.e. up to 200  $\mu$ L, 0.455 mg, of the 2.275 mg/ml finasteride topical skin spray solution) once a day and oral placebo for 24 weeks; (2) excipient group (181 patients): topical excipient (hydroxypropyl chitosan solution without finasteride) and oral placebo once a day for 24 weeks; and (3) oral finasteride group (84 patients): topical excipient and 1 mg oral finasteride once a day for 24 weeks. The primary efficacy endpoint of the clinical trial was hair growth as assessed by target area hair count at week 24. The secondary efficacy endpoints of the clinical trial included hair growth as assessed by apical target area hair count at week 12, apical target area hair width at week 12 and week 24, male hair growth questionnaire assessed by the patients at week 12 and week 24, change in apical hair from baseline (patient hair growth/shedding) assessed by the investigator at week 12 and week 24, and change in apical hair from baseline (patient hair growth/shedding) assessed by blinded assessors at week 12 and week 24.

<u>Trial Status.</u> The Phase III clinical trial was initiated on August 2, 2016 and completed on March 5, 2018.

Safety Data. The most common treatment emergent adverse events are rhinopharyngitis (15.5% in the CU-40102 group, 13.3% in the excipient group, and 17.9% in the oral finasteride group) and headache (9.4% in the CU-40102 group, 11.0% in the excipient group, and 9.5% in the oral finasteride group). The overall incidence of treatment emergent adverse events in the CU-40102 group (41.4%) was similar to that in the excipient group (42.0%) and slightly lower than that in the oral finasteride group (48.8%). The incidence of treatment emergent adverse events leading to early study withdrawal was also similar between the CU-40102 group and excipient group (2.8% vs. 2.2%) and lower than in the oral finasteride group (7.1%). Moreover, all treatment groups were well tolerated with only mild or moderate treatment emergent adverse events occurring in the vast majority of patients. As for the incidence of sexual adverse events (such as decreased libido, loss of libido, erectile dysfunction, and ejaculation dysfunction) was low in all treatment groups: five patients in the CU-40102 group (2.8%), seven patients in the excipient group (3.9%), and five patients in the oral finasteride group (6.0%). In addition, the clinical trial showed no clinically meaningful changes from baseline for all vital signs and physical examination results (blood pressure, heart rate, temperature, weight, height, and body mass index) and the mean values of all assessed clinical laboratory test parameters (hematology, blood biochemistry, and/or urinalysis), and no differences between treatment groups.

Efficacy Data. The registrational Phase III clinical trial met its primary efficacy endpoint and confirmed the efficacy. The primary efficacy endpoint showed that the least squares method for mean change of target area hair count (within a 1 cm<sup>2</sup> circular target area) compared with the baseline in the CU-40102 group at week 24 (i.e., corrected mean change: + 20.2 hairs) was significantly greater than in the excipient group (+ 6.7 hairs; mean difference in the least squares: 13.6 hairs) and similar to the oral finasteride group (+ 21.1 hairs). In addition, analyses across subgroups consistently showed that the efficacy of CU-40102 was comparable across geographic regions, independent of the number of sprays used. As for the secondary efficacy endpoint, almost all secondary efficacy variables in the CU-40102 group were significantly superior than in the excipient group: the men's hair growth questionnaire parameter scores (i.e., hair appearance, hair growth, slowing hair loss, hairline at the front of the head, hairline at the top of the head and overall hair), the results of the investigator's assessment of change in patient hair growth/hair loss compared to baseline, and the results of the blinded assessor's assessment of change in patient hair growth/hair loss compared to baseline.

#### Licensing and Post-licensing R&D

On November 2, 2020, we entered into an agreement (the "**CU-40102 Agreement**") with Polichem S.A. ("**Polichem**"). Pursuant to the CU-40102 Agreement, Polichem granted us an exclusive, royalty-bearing, non-assignable and non-sublicensable license regarding the licensed patents, know-how and trademarks 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 consisting of Mainland China, Taiwan, Hong Kong and Macao. For more details about the agreement, see "– Collaboration and Licensing Arrangements – CU-40102 Agreement."

We are currently conducting clinical trials for CU-40102 to determine its safety and efficacy. Furthermore, in order to conduct the pilot commercialization of CU-40102 in Boao Pilot Zone, we collaborated with an independent third party agency in Hainan, identified a target collaboration institution located in the Boao Pilot Zone, determined the urgently needed use for CU-40102, monitored and advanced the collaboration and pilot commercialization of CU-40102. Considering that we are not the marketing authorization holder of CU-40102, we should report all non-compliance and drug safety issues during commercialization activities to Polichem S.A. According to the CU-40102 Agreement, we are not mandated to take responsibility for non-compliance and drug safety issues resulting from the activities of Polichem S.A.

#### Clinical Development Plan

We, as the sole sponsor, are currently conducting a Phase I clinical trial for PK and a registrational Phase III clinical trial for the treatment of androgenetic alopecia for CU-40102 in China and we have commenced pilot commercialization of CU-40102 in Lecheng, Hainan. For more details of the regulatory framework of CU-40102 for pilot commercialization, see "Regulatory Overview – Regulations on Pharmaceutical Product Development, Approval and Registration – Regulations on the Clinical Trials and Registration of Drugs – Import of Urgently Needed Drug in Boao Pilot Zone" in this Document. We commenced pilot

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# BUSINESS

commercialization of CU-40102 in August 2021 and recorded revenue of RMB81.9 thousand from sales of CU-40102 in the year ended December 31, 2022. Our Phase III clinical trial of CU-40102 for the treatment of androgenetic alopecia in Mainland China has completed patient enrollment. We expect to complete the primary endpoint read-out for the Phase III clinical trial in the fourth quarter in 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in the fourth quarter of 2024. We have the right to obtain market authorization on behalf of Polichem, and Polichem or its designee will be the holder of the marketing authorization in Greater China. Under the pilot commercialization of CU-40102 in Lecheng, Hainan, the product is provided to patients in urgent need by qualified medical institutions. The qualified medical institution determines the pricing and commercialization strategy. Once the commercialization approval from NMPA is obtained, we plan to formulate and adjust the pricing and commercialization strategy in order to market the product in Greater China. Considering that CU-40102 is the first and only topical finasteride product approved for androgenetic alopecia treatment globally and the only topical finasteride under clinical development in China, the patients base can be significant larger than that in Hainan, CU-40102 is therefore expected to be priced higher than other direct market competitors or the closest comparable product. After obtaining the approval from the NMPA, we plan to take into account a number of factors, such as the market size, prevalence of population, economic development level, the price of the approved product, patient demand and affordability and retail prices in the country of origin and price sensitivity in Greater China in determining the pricing strategy of CU-40102. We plan to maintain a holistic and consistent business strategy for one specific product such as the higher price strategy of CU-40102 and also a holistic and consistent business strategy for the entire pipeline product portfolio, including CU-20401, CU-40102 and other products. Our Directors believe that the holistic and consistent business strategy for both one specific product and the entire pipeline product portfolio helps to minimize the impact of price fluctuations of an individual specific product on our overall future development. Thus, the change in the pricing and commercialisation strategy for CU-40102 would not have a material impact to our overall sales performance.

#### Material Communications with Competent Authorities

We filed an IND application for the Phase III clinical trial for CU-40102 to the NMPA on July 14, 2021 based on the previous completed Phase III clinical trial data sponsored by Polichem. The NMPA issued the IND approval for the Phase III clinical trial on September 27, 2021 and also recommended conducting a supplemental PK study in order to examine the metabolism profile after CU-40102 treatment. Therefore, we initiated both Phase I clinical trial for PK study that is equivalent to the supplemental PK study as recommended by the NMPA and Phase III clinical trial for safety and efficacy for CU-40102. The approval for pilot commercialization of CU-40102 from Hainan Medical Products Administration was received on July 27, 2021. During the Track Record Period and up to the Latest Practicable Date, we are not aware of any regulatory non-compliance issues or drug safety concerns and complaints, product recalls and medical incidents for CU-40102.

We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-40102 SUCCESSFULLY.

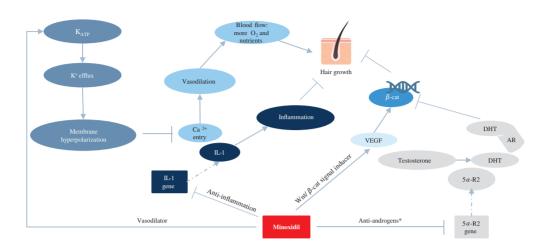
#### CU-40103: Pre-clinical Stage Minoxidil Foam

CU-40103 is a self-developed topical minoxidil foam for the treatment of alopecia. CU-40103 is expected to adopt a differentiated elegant foam formulation and become an alternative addition to the existing minoxidil tinctures and liniments in the market. It features a much less greasy texture that enables better user experience. We are currently conducting the pre-clinical study of CU-40103. We plan to submit an ANDA for alopecia to the NMPA in the third quarter of 2024. We believe that CU-40103 has the potential to capture enormous commercial benefit from its differentiated dosage form as well as the growing scalp disease treatment demands in China.

#### Mechanism of Action

Minoxidil is a small molecule peripheral vasodilator and converts into an active form minoxidil sulphate with the help of sulfotransferase. Minoxidil promotes hair growth in multiple ways. First, it acts as an adenosine 5'-triphosphate-sensitive potassium channel opener to result in outflow of potassium and hyperpolarization of cell membranes. It accordingly relaxes muscle walls and widens blood vessels, allowing blood to flow more easily to the scalp and hair follicles and prompting more nutrients and oxygen to reach the hair follicles. Second, the hair cycle is a highly regulated process consisting of four distinct phases: anagen (growth phase), catagen (transitional phase signaling the end of active hair growth), telogen (resting phase) and exogen phase (shedding phase). Minoxidil contains a nitric oxide moiety and may act as a nitric oxide agonist. This may shorten the resting phase of hair follicles and promote hair follicles in the resting phase to enter the growth phase as early as possible, thus achieving the effect of promoting hair growth. Third, minoxidil stimulates prostaglandin E2 production, enhances prostaglandin E2 receptor expression, but inhibits prostacyclin production, thereby enabling hair follicles to grow continuously. In vitro minoxidil treatment in monocultures of various skin and hair follicle cell types stimulates cell proliferation. In vitro minoxidil treatment also resulted in a 0.22-fold change for 5 alpha-reductase, suggesting an anti-androgenetic effect of minoxidil to stimulate hair growth.

The diagram below illustrates the mechanism of action minoxidil, the active ingredient of CU-40103:



Abbreviations: K: potassium; IL: interleukin; Ca: calcium;  $O_2$ : oxygen; VEGF: vascular endothelial growth factor; Wnt: wingless-related integration site;  $\beta$ -cat: beta-catenin;  $5\alpha$ -R2: 5 alpha-reductase; DHT: dihydrotestosterone; AR: androgen receptor

Source: Frost & Sullivan analysis

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-40103 SUCCESSFULLY.

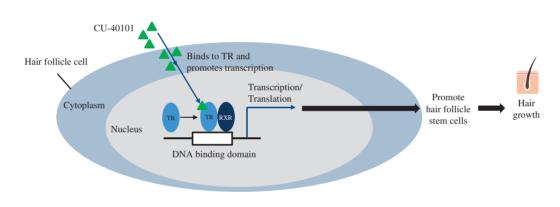
# CU-40101: Phase I Clinical-Stage Topical Liniment of Small Molecule Hormone Receptor Agonist

#### Overview

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-40101 is differentiated from current available androgenetic alopecia treatment in its mechanism of action and the potential to be used in both male and female patients. We are currently running a Phase I dose escalation trial in China to evaluate the safety and tolerability of CU-40101 as an alternative therapeutic agent in promoting hair growth in patients with androgenetic alopecia. We enrolled the first patient in a Phase I clinical trial to treat androgenetic alopecia in September 2022 in China, and we expect to complete the Phase I clinical trial in the second quarter of 2024.

#### Mechanism of Action

CU-40101, N1-(3,5-dichloro-4-(3-(4-fluorobenzyl)-4-hydroxyphenoxy)phenyl)-N2-hydroxyoxalamide, is a potent small molecule thyroid hormone receptor agonist. CU-40101 binds to thyroid hormone receptor in hair follicle cells and induces hair growth by promoting hair follicle stem cell to initiate hair growth, a programmed regeneration process that runs automatically once initiated. The skin is a recognized target of thyroid hormones. The biological activity of thyroid hormones is mediated through the nuclear thyroid hormone receptor. These effects are mediated in part through ligand-specific interactions of the thyroid hormone receptor with its partner retinoid X receptor and the binding of these transcription factors to specific promoter regions of the thyroid hormone response gene. The expression of thyroid hormone receptor is localized in the nuclei of human hair follicle outer hair root sheath and dermal papilla cells, suggesting a role for thyroid hormones in hair growth. Thyroid hormones have been shown to stimulate epidermal proliferation and hair growth in animals. On the other hand, hypothyroidism causes hair loss, with symptoms of lusterless, brittle hairs and increased percentage of resting hair follicles.



The diagram below illustrates the mechanism of action of CU-40101:

Source: Frost & Sullivan analysis

#### Competitive Advantages

We believe that CU-40101 has the following advantages:

#### Stimulating Growth of Hair Follicles in Resting Phase

The pre-clinical studies have shown that CU-40101 can stimulate growth of hair in resting phase in a dose-dependent manner when applied topically. In the *in vivo* hair growth model in C3H mice, the hairs on the dorsal skin are in resting phase from about 6-14 weeks after birth. The hairs cycle phase on the dorsal skin of C3H mice at about 7 weeks of age is in the resting phase, characterized by pink skin, and the hair on the lower back of the mice is shaved to prepare the skin for administration. The vehicle (propylene glycol/ethanol, 30/70, negative control) or test compounds, including CU-40101 and minoxidil, is applied to an area near the base of the tail. Application of CU-40101 induced hair growth prior to the next natural growth phase, presumably by activating hair follicles in resting phase into the growth phase. In comparison, hair growth was not observed in any mice in the vehicle control or minoxidil groups, suggesting that minoxidil had no effect at all on the hair follicles in resting phase of the mice experimental model.

#### Low Systemic Drug Exposure

Pre-clinical studies showed that topical administration of CU-40101 solution at doses of 0.28 and 1.4 mg/kg (0.05% and 0.25%) in British guinea pigs caused no skin or systemic allergic reactions. The pre-clinical pharmacokinetic studies showed that after a single topical application of CU-40101 at 0.001-0.02 mg/mouse or 0.11-2.2 mg/pig, plasma CU-40101 concentrations were below the limit of quantification by 0.1 ng/mL.

### Licensing

On April 17, 2020, we entered into a licensing agreement (the "**CU-40101 Agreement**") with TechnoDerma Medicines Inc. ("**TechnoDerma**"). 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. For more details, see "– Collaboration and Licensing Arrangements – CU-40101 Agreement."

# **Clinical Development Plan**

We are currently conducting a Phase I clinical trial to evaluate the safety, tolerability and pharmacokinetics of single and multiple doses of CU-40101 liniment formulation in adult male patients with androgenetic alopecia in China. We expect to enroll 62 patients, including 32 patients of single-dose dose escalation cohort and 30 patients of multi-dose dose escalation cohort. The primary endpoints for the Phase I trial are to evaluate the safety, immunogenicity, tolerability and pharmacokinetics of single and multiple doses of CU-40101 liniment formulation. Additional endpoints include hair count change at target area. We enrolled the first patient in the Phase I clinical trial in September 2022 in China, and we expect to complete the Phase I clinical trial in the second quarter of 2024.

# Material Communications with Competent Authorities

We filed an IND application for a Phase I clinical trial to evaluate the safety, tolerability and pharmacokinetics of single and multiple doses of CU-40101 liniment formulation with the NMPA on September 26, 2021, and received the NMPA approval to conduct Phase I clinical trial on December 17, 2021.

We had not received any relevant regulatory agency's objections to our clinical development plan as of the Latest Practicable Date.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-40101 SUCCESSFULLY.

#### CU-40104: Pre-clinical Stage Topical Dutasteride

CU-40104 is a self-developed topical dutasteride to treat androgenetic alopecia. Although dutasteride has not been approved for androgenetic alopecia in China, it has been approved by the FDA for the treatment of alopecia in the U.S. The FDA approved dutasteride for the indication of male symptomatic benign prostatic hyperplasia. In clinical trials, oral dutasteride developed by GSK plc has demonstrated superior clinical data with a statistically significant difference in treating androgenetic alopecia compared to oral finasteride. 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 and is expected to be approved for the treatment of androgenetic alopecia. We are currently conducting the pre-clinical study of CU-40104. We, as the sole sponsor of the Phase I clinical trial, plan to submit an IND application to the NMPA in the fourth quarter of 2024.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CU-40104 SUCCESSFULLY.

#### SKIN DISEASES AND CARE

Current treatments for common skin diseases include systemic agents, topical therapies and physical therapy. However, due to drug resistance from long treatment duration, the lack of novel or effective treatments and the unclear pathology of skin diseases, current therapies are unlikely to have durable and consistent response and patients are generally prone to relapse. We are currently developing three skin disease products, including CU-10201 for the treatment of moderate to severe acne vulgaris, CU-10101 for the treatment of atopic dermatitis and CU-10401 for the treatment of psoriasis, to capture the growing market of skin diseases and care products in China. It is estimated that the skin diseases and care market will increase from RMB352.6 billion in 2021 to RMB493.3 billion in 2025, representing a CAGR of 8.8%, and further increase to RMB740.2 billion in 2030, representing a CAGR of 8.5% from 2025 to 2030, according to Frost & Sullivan. To complement our current skin diseases and care product candidates under development, we, one of our entities in Mainland China as the contracting party, also engage third parties to develop, manufacture and then sell certain skin care products, including facial masks, creams, toners, sprays, serums and gels (the "Routine Skin Care Products") through Tmall e-commerce platform, for daily care and post-treatment maintenance in the PRC.

#### Key Product CU-10201: Phase III Clinical-Stage Topical Minocycline Foam

#### Overview

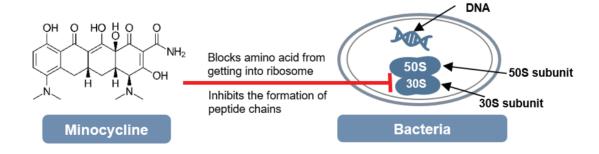
CU-10201 is an in-licensed product and the first and only topical minocycline approved for acne vulgaris treatment globally. We in-licensed CU-10201 from Foamix Pharmaceuticals Ltd. in April 2020. Foamix was a subsidiary of Menlo Therapeutics Inc. (Nasdaq: MNLO), whose corporate name was changed to VYNE Therapeutics Inc. (Nasdaq: VYNE) in late 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<sup>TM</sup>, with Foamix Pharmaceuticals Inc. as the marketing authorization holder. Minocycline exhibits broad-spectrum antibacterial activity. The currently available minocycline products are primarily oral medications. With a topical formulation, CU-10201 can be delivered to the acne lesions, thereby significantly reducing systemic exposure and incidence of associated adverse events. We are currently evaluating the therapeutic potential of CU-10201 for the treatment of moderate to severe acne vulgaris in a Phase III clinical trial in China. We expect to complete the primary endpoint read-out for the Phase III clinical trial in the first quarter of 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in the fourth quarter of 2024.

#### Mechanism of Action

Minocycline is a widely applied antibiotic and can be used to treat a number of bacterial infections and skin diseases, including acne vulgaris. Minocyclines blocks amino acid from getting into ribosome such that the formation of peptide chains of bacteria is inhibited. Acne vulgaris has a multifactorial etiology including inflammation and infection. Obstruction of hair follicles and the accompanying sebaceous glands, follicular colonization by *Cutibacterium acnes* and production of multiple pro-inflammatory cytokines may lead to the formation of non-inflammatory and inflammatory lesions. Minocycline exhibits broad-spectrum antibacterial activity against a wide range of microorganisms including *C. acnes* and other reported pathogens in skin infections, such as *Staphylococcus aureus*, *Streptococcus spp.*, *Pseudomonas aeruginosa* and methicillin-resistant strains of *Staphylococcus epidermidis*. Minocycline also possesses anti-inflammatory properties that may help alleviate acne vulgaris by exhausting TNF $\alpha$ /INF- $\gamma$  and downregulating pro-inflammatory cytokine secretion to inhibit apoptosis.

The diagram below illustrates the mechanism of action of CU-10201:



Source: Frost & Sullivan analysis

#### Market Opportunities

Acne vulgaris is a chronic inflammatory dermatosis notable for open or closed comedones and inflammatory lesions, such as papules, pustules, or nodules. Acne vulgaris is a common skin disease in particular in adolescents and young adults. It can cause significant physical and psychological morbidity, such as permanent scarring, poor self-image, depression and anxiety. According to Frost & Sullivan, the prevalence of acne vulgaris in China increased from 118.5 million in 2017 to 120.5 million in 2021, representing a CAGR of 0.4%, and is expected to reach 122.0 million in 2025, representing a CAGR of 0.3% from 2021 to 2025 and 123.1 million in 2030, representing a CAGR of 0.2% from 2025 to 2030, suggesting a large market size in China.

Treatment options include hormonal agents (anti-androgen treatments), topical therapies, systemic antibiotics and isotretinoin. However, the use of antibiotics, especially oral antibiotics, faces the rising problem of drug resistance, which not only undermines the clinical efficacy of acne treatment, but also leads to the emergence of other resistant bacteria strains through plasmid transmission of resistance genes, thus increasing the risk of multi-drug resistant infections such as upper respiratory tract infections and pneumonia. Other common topical therapies for acne including benzoyl peroxide, topical retinoids and various types of acids often cause some degree of skin irritation especially at early stage of use. These treatments need to be started with a lower dose and gradually increased over time. Such process can be time consuming, and many patients fail to build up skin tolerance or self-identify and apply the appropriate amount of drugs that exerts clinical efficacy while not inducing serious skin irritation. Failure in doing so leads to poor compliance to the therapy and hence lack of efficacy. Another treatment option for moderate to severe acne is oral isotretinoin with a variety of limitations, including side effects such as dry lips, dry eyes, depression, hair loss, birth defects, strict contraindication for pregnant females, and long duration of treatment. It usually takes months to show desired effects after administration and the patients may experience breakouts during initial stage due to the side effects.

Our Key Product CU-10201, is the first and only topical minocycline approved for acne vulgaris treatment globally. Minocycline is a tetracycline antibiotic used to treat a number of bacterial infections and acne vulgaris. Compared to other major anti-acne antibiotics, topical minocycline foam has fewer side effects, a lower rate of drug resistance, and likely higher patient compliance. In addition, the highly lipophilic nature of minocycline allows it to concentrate in hair follicles and sebaceous glands.

#### Competitive Advantages

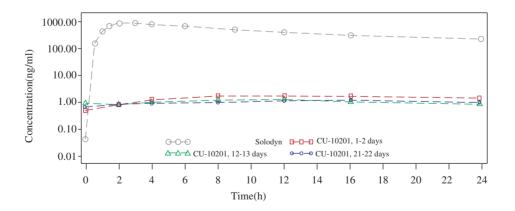
We believe CU-10201 has the following advantages:

#### Low Systemic Drug Exposure

CU-10201 is the foam form of 4% minocycline hydrochloride. A pharmacokinetic study comparing topical administration of CU-10201 and oral administration of solodyn, the minocycline hydrochloride extended-release tablet, showed that CU-10201 exhibited significantly lower systemic drug exposure. 30 subjects received a single dose of Solodyn (Stage 1) at approximately 1 mg/kg, and after one week, the subjects received CU-10201 (Stage 2) for 21 days, with topical administration of around 4g CU-10201 on face, neck, upper chest, upper back, shoulders and upper arms of subjects. Blood samples were collected for both stages to determine the minocycline plasma concentrations.

Compared to oral minocycline medication solodyn, the topical formulation of CU-10201 exhibited significantly lower systemic drug exposure, as indicated by the plasma drug concentration showed in the following figure. The relative bioavailability of minocycline of CU-10201 compared to solodyn was 0.126% on day 12 and 0.131% on day 21 based on Cmax, and 0.134% and 0.137% based on AUC. The systemic exposure amount of minocycline of daily administration of CU-10201 at a maximum dose of 4g for up to 21 days was 730-794 times lower than that of oral administration of solodyn at around 1 mg/kg minocycline.

# Average plasma drug concentration of minocycline of acne patients after oral application of Solodyn<sup>®</sup> and topical application of CU-10201 – time curve (semi logarithmic ratio)



Source: Company data based on Phase III clinical trial of CU-10201 for moderate-to-severe acne vulgaris sponsored by Foamix

#### Strong Antibacterial Activity against C. Acnes and Low Incidence of Resistance

*C. acnes* plays an important role in the pathogenesis of acne vulgaris. CU-10201 has very broad-spectrum antibacterial activity against a variety of microorganisms, including *C. acnes*, and other microorganisms reported in various skin infections, In the *in vitro* antibacterial activity study, CU-10201 has the largest inhibition of diameter among CU-10201, placebo and fucidin (a topical antibiotic commonly used to treat inflammatory lesions in acne vulgaris and other bacterial skin infections).

In addition, spontaneous resistance to CU-10201 occurred at a frequency of  $<1 \times 10^{-8}$  in seven *C. acnes* strains. After 15 consecutive passages of *C. acnes*, CU-10201 still had potent antibacterial activity against *C. acnes*. Therefore, *C. acnes* has low incidence of resistance to minocycline treatment.

#### Summary of Clinical Trial Results

The clinical pharmacology, efficacy and safety trials of CU-10201 have been conducted through a clinical development program consisting of 11 completed clinical trials conducted by Foamix. We are conducting a bridging Phase III clinical trial for efficacy and safety in patients with moderate-to-severe acne vulgaris. Among these trials, CU-10201 was generally well-tolerated in patients and showed evidence of efficacy. We present the results of key clinical trials below.

# Phase III Bridging Clinical Trial of CU-10201 for Moderate-to-Severe Acne Vulgaris Sponsored by us

<u>Overview.</u> This was a multi-center, randomized, double-blind, placebo-controlled Phase III bridging clinical trial in patients  $\geq 9$  years old with moderate-to-severe acne vulgaris. The trial is designed to assess the efficacy and safety of the CU-10201 in China. The regulatory authority of this trial is the NMPA.

<u>Trial design</u>. The CU-10201 group was treated once-daily with CU-10201 by smearing the facial acne site for 12 consecutive weeks. The control group was treated once-daily with the vehicle by smearing the facial acne site for 12 consecutive weeks. The primary objective of the Phase III clinical trial was to test the safety and efficacy of CU-10201 against vehicle after 12-week treatment of acne. The primary efficacy endpoint of this clinical trial was the change of inflammatory lesion count against the baseline after 12-week treatment. The secondary efficacy endpoints of this clinical trial included the successful rate based on investigator general assessment (IGA) score after 12-week treatment, the change of inflammatory lesion count against the baseline after 4- and 8-week treatment. The safety endpoints included treatment emergent adverse events, clinical laboratory tests, physical examination, vital signs measurements, and local skin tolerance assessment scores (including erythema, dryness, peeling, and hyperpigmentation).

<u>Trial status.</u> We initiated the trial in April 2021 and planned to enroll 372 patients with moderate-to-severe acne vulgaris. All 372 patients had been enrolled by the end of June 2022. We are collecting clinical data, and no preliminary clinical result is available for analysis.

# Phase III Clinical Trial of CU-10201 for Moderate-to-Severe Acne Vulgaris Sponsored by Foamix

<u>Overview.</u> This was a randomized, multi-center, double-blind, placebo-controlled, 2-arm, 12-week Phase III clinical trial of efficacy and safety for the treatment of patients with moderate to severe acne vulgaris in the U.S. The regulatory authority of this trial is the FDA. All primary endpoints were met.

<u>Trial design.</u> The patients were randomized to receive either CU-10201 or placebo treatments. The endpoints were to evaluate efficacy, including acne lesion count and investigator's global assessment. Additional efficacy endpoints included a subject satisfaction questionnaire with eight questions. The safety evaluation included treatment emergent adverse events, clinical laboratory tests, physical examination, vital signs measurements, and local skin tolerance assessment scores (including erythema, dryness, peeling, and hyperpigmentation).

<u>Trial status.</u> Foamix enrolled 1,488 patients aged between 9 to 66 years old and completed the clinical trial in 2018.

<u>Safety data.</u> The frequency of treatment emergent adverse events and other safety-related effects was low and no clinically significant trends were observed. The topical treatment with CU-10201 or the placebo topical treatment for 12 weeks was shown to be safe and well tolerated for patients with moderate to severe acne vulgaris. The majority of reported treatment emergent adverse events were mild and not treatment-related. No other safety indicators (e.g., clinical laboratory tests, vital signs tests, physical examinations) demonstrated any safety concerns with CU-10201 topical treatment.

Efficacy data. In the analysis of the primary endpoint of change from baseline in inflammatory lesion counts, the estimated mean change from baseline to 12 weeks was 16.93 in the CU-10201 treatment group and 13.40 in the placebo treatment group. In the analysis of the primary endpoint of treatment success based on investigator's global assessment scores, the successful treatment rate at 12 weeks reached 30.80% in the CU-10201 treatment group and 19.63% in the placebo treatment group. In the subject satisfaction questionnaire with eight questions administered at 12 weeks, 31.8% of patients in the CU-10201 treatment group were satisfied and 34.9% were very satisfied with the product and its acne treatment effects, compared with 20.8% and 24.6% in placebo treatments group, respectively. The treatment with CU-10201 for 12 weeks was superior than placebo treatment in reducing the number of inflammatory and non-inflammatory acne lesions, and achieved treatment success as evaluated by investigator's global assessment.

#### Licensing and Post-licensing R&D

On April 21, 2020, we entered into a licensing agreement (the "**CU-10201 Agreement**") with Foamix. Pursuant to the CU-10201 Agreement, Foamix grants to us an exclusive, royalty-bearing license, which includes 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 was a subsidiary of Menlo Therapeutics Inc. (Nasdaq: MNLO), whose corporate name was changed to VYNE Therapeutics Inc. (Nasdaq: VYNE) in late 2020. VYNE Therapeutics Inc. had assigned the rights and obligations under the CU-10201 Agreement to Journey Medical Corporation effective as of January 12, 2022. For more details about the agreement, see "– Collaboration and Licensing Arrangements – CU-10201 Agreement."

We are currently conducting clinical trials for CU-10201 to determine its safety and efficacy. Furthermore, in order to conduct the pilot commercialization of CU-10201 in Boao Pilot Zone, we collaborated with an independent third party agency in Hainan, identified a target collaboration institution located in the Boao Pilot Zone, determined the urgently needed use for CU-10201, monitored and advanced the collaboration and pilot commercialization of CU-10201. Considering that we are not the marketing authorization holder of CU-10201, any non-compliance and drug safety issue would need to be reported to the marketing authorization holder and according to the CU-10201 Agreement, we are not mandated to take responsibility for such issue.

#### **Clinical Development Plan**

We, as the sponsor, are currently conducting a bridging Phase III clinical trial for CU-10201, and we have commenced pilot commercialization of CU-10201 in Lecheng, Hainan since July 2021. A bridging clinical trial is a clinical trial performed in a new region to provide safety and efficacy data that allow extrapolation of the foreign clinical data to the population in the new region. We filed the bridging Phase III clinical trial IND application in January 2021 based on data from the previous completed Phase III clinical trial sponsored by Foamix in order to initiate Phase III clinical trial directly. We expect to complete the primary endpoint read-out for the Phase III clinical trial in the first quarter of 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in China in the fourth quarter of 2024. Foamix is the marketing authorization holder and we are acting as agent of Foamix to fulfil Foamix' obligation. Under the pilot commercialization of CU-10201 in Lecheng, Hainan, the product is provided to patients in urgent need by qualified medical institutions. The qualified medical institution determines the pricing and commercialization strategy. Once the commercialization approval from NMPA is obtained, we plan to change the pricing and commercialization strategy in order to market the product in Greater China. CU-10201 is expected to be priced higher than direct market competitors or the closest comparable product. After obtaining the approval from the NMPA, we plan to take into account a number of factors, such as the market size, prevalence of population, economic development level, the price of the approved product, patient demand

and affordability and retail prices in the country of origin and price sensitivity in Greater China in determining the pricing strategy of CU-10201. Our Directors believe that we have maintained a holistic and consistent business strategy for our products which helps to minimize the impact on overall future development due to price fluctuations of individual products. Thus, the change in the pricing and commercialisation strategy for CU-10201 would not have a material impact to our overall sales performance.

#### Material Communications with Competent Authorities

We filed an IND application to the Phase III clinical trial to assess the efficacy and safety of CU-10201 treating moderate-to-severe acne vulagris to NMPA in January 2021 and received IND approval in April 2021. The approval for pilot commercialization of CU-10201 from Hainan Medical Products Administration was received on July 27, 2021. For more details of the regulatory framework of CU-10201 for pilot commercialization, see "Regulatory Overview – Regulations on Pharmaceutical Product Development, Approval and Registration – Regulations on the Clinical Trials and Registration of Drugs – Import of Urgently Needed Drug in Boao Pilot Zone" in this Document. We commenced the pilot commercialization of CU-10201 for the year ended December 31, 2022. We did not record revenue in 2021 because under our arrangement with our Hainan distributor, the distributor is entitled to return the products based on agreed grounds resulting in that the revenue would only be recognized when the distributor sells the products to the end users. During the Track Record Period and up to the Latest Practicable Date, we are not aware of any regulatory non-compliance issues or drug safety concerns and complaints, product recalls and medical incidents for CU-10201.

We had not received any relevant regulatory agency's objections to our clinical trials as of the Latest Practicable Date.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-10201 SUCCESSFULLY.

#### CU-10101: Pre-clinical Stage Small Molecule Drug

#### Overview

CU-10101 is an in-licensed non-hormonal, small molecule drug targeting atopic dermatitis. We in-licensed CU-10101 in from Wuhan Yingnashi Pharmaceutical Co., Ltd. (武 漢英納氏藥業有限公司) in November 2019. For atopic dermatitis, the therapeutic options are limited and mainly include corticosteroids. calcineurin inhibitors. systemic immunosuppressants, and targeted biologics and small-molecule drugs. Topical steroids are the most commonly prescribed therapies for atopic dermatitis. Most targeted biologics and small molecule drugs for atopic dermatitis require subcutaneous or oral administration, where systemic exposure causes a higher risk of side effects and lower patient compliance than topical treatments. The first FDA-approved topical JAK inhibitor for the treatment of atopic dermatitis, opzelura (ruxolitinib) cream, developed by Incyte, can only be used for short-term

and non-continuous chronic treatment of patients with mild to moderate atopic dermatitis. The non-hormonal properties of CU-10101 may reduce the side effects and restrictions associated with corticosteroids and it features a topical formulation that can reach the affected areas directly. We are conducting the pre-clinical study of CU-10101. We plan to submit an IND application to the NMPA in the second quarter of 2024.

#### Market Opportunities

Atopic dermatitis offers a wide clinical spectrum ranging from minor forms such as pityriasis alba (dry depigmented patches) or hand eczema to major forms with erythrodermic rash. Pruritus and chronic or relapsing eczematous lesions with typical shape and distribution are the major symptoms. Atopic dermatitis can have a detrimental effect on the quality of life of patients and their families on social, academic, and occupational aspects due to strong and lasting itching and the appearance of dermatitis lesions. Atopic dermatitis places a considerable financial burden on patients, their families, and society as a whole through direct medical costs and decreased productivity. According to Frost & Sullivan, the prevalence of atopic dermatitis in China increased from 62.4 million in 2017 to 69.1 million in 2021, representing a CAGR of 2.6%, and is expected to reach 75.2 million in 2025, representing a CAGR of 2.2% from 2021 to 2025 and 81.7 million in 2030, representing a CAGR of 1.7% from 2025 to 2030, suggesting a large market size in China.

#### Competitive Advantages

We believe CU-10101 has the following advantages:

#### Promising Potency against Atopic Dermatitis

The in vitro cell model efficacy test results demonstrated that CU-10101 with active pharmaceutical ingredient 3,5-dihydroxy-4-isopropyldiphenylethane has favorable efficacy in several classic atopic dermatitis models, such as 3D epidermal skin model, macrophage inflammation model and keratinocyte model. In the Poly I:C+LPS stimulated 3D epidermal skin model (Epikutis<sup>®</sup>) test, four groups of the skin model were treated with 1) culture medium (for blind control group), 2) PolyI:C+LPS stimulation solution (for negative control group), 3) 0.01% dexamethasone (a corticosteroid hormone) or 50µM WY14643 (an agonist of peroxisomal proliferation activates receptors) (for positive control group) and 4) 0.0039mg/mL  $(25\mu L)$  and 0.001 mg/mL  $(25\mu L)$  CU-10101 (for test group). The results showed that both 0.0039mg/mL and 0.001mg/mL CU-10101 improve tissue morphology, inhibit the secretion of thymic stromal lymphopoietin (TSLP) and enhance the expression of barrier-related proteins filaggrin (FLG) and loricrin (LOR), thus achieving soothing effects. The macrophage inflammation model test showed the anti-inflammation effects and soothing effects for CU-10101 by inhibiting IL-1 $\beta$ , IL-6, TNF $\alpha$ , PGE2 and NO levels, and the keratinocyte model test showed soothing effects by inhibiting TRPV1 (transient receptor potential cation channel subfamily V member 1) protein level. Thus, CU-10101 has soothing effects and antiinflammation effects to potentially achieve favorable efficacy for atopic dermatitis treatment.

#### Optimized Formulation and Improved Atopic Dermatitis Patients' Skin Friendliness

The ointment formulation has been optimized to mitigate the photo-instability nature of the compound itself. Atopic dermatitis patients have impaired skin barrier function. The ointment dosage form is believed to improve skin barrier function. The topical dosage forms of approved atopic dermatitis medications include ointment, cream, gel and solution. Ointment is an oil-based semisolid preparation that comprises less than 20% water and volatiles, and more than 50% hydrocarbons, waxes, or polyols as the vehicle. Ointment is thicker and has a longer duration of action than other common dosage forms.

#### Licensing and In-licensing R&D activities

Before in-license in November 2019, the licenser obtained a patent for CU-10101 based on their chemical works and efficacy studies. After in-licensing, we conducted analysis from pre-clinical and CMC perspectives and prepared research and development plan. We have devoted considerable amount of time and resources to the R&D work of CU-10101, which includes, among others, development of a new ointment formulation for the CU-10101 compound, and pre-clinical *in vitro/vivo* efficacy studies in cells and animal.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-10101 SUCCESSFULLY.

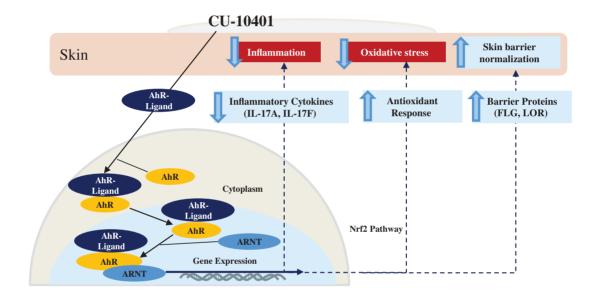
#### CU-10401: Pre-clinical Stage Generic Tapinarof Cream

#### Overview

CU-10401, an acquired 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. (武 漢英納氏藥業有限公司) in June 2020. Current treatments for psoriasis include topical therapy, phototherapy and systemic therapies. Topical treatments are usually the first-line treatments used for mild to moderate psoriasis, but it may take up to six weeks before there is a noticeable effect. Phototherapy requires routine visits to hospitals with phototherapy equipment and can bring significant inconvenience to patients' daily life. Systemic therapies are not able to induce clinical responses in all patients and may cause serious side effects including higher risk of severe infection. As a result, there has been unmet needs for safer and more effective treatments. 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. Compared with another commonly used topical drug, calcipotriol, tapinarof has a lower recurrence rate without risks of elevated serum calcium which can be caused by calcipotriol. CU-10401 has the potential to become the first generic tapinarof cream approved in China. We are currently conducting the pre-clinical study of CU-10401. We plan to submit an ANDA to the NMPA in 2026.

#### Mechanism of Action

Tapinarof can act as an AhR-ligand to enter into the cell's cytoplasm once applied to the skin. AhR-ligand can bind and activate the AhR to translocate into the cell's nucleus. The ligand-activated AhR then heterodimerizes with the aryl hydrocarbon receptor nuclear translocator (ARNT) to form ligand-AhR-ARNT complex which can bind to DNA to modulate gene expression. In such a way, T helper type 17 cytokines can be significantly reduced to mediate inflammation. Meanwhile, antioxidant response is increased via NF-E2-related factor 2 (Nrf2) pathway as well as direct reactive oxygen species scavenging by tapinarof to decrease oxidative stress. Regulation of skin barrier protein expression such as filaggrin (FLG) and loricrin (LOR) upon the binding between ligand-AhR-ARNT complex and DNA can promote skin barrier normalization.



Source: Literature Review, Frost & Sullivan analysis

#### Market Opportunities and Competitive Advantages

Psoriasis is a common, chronic, systemic, immune-mediated inflammatory disease. It speeds up the division cycle of skin cells, causing cells to build up rapidly on the surface of the skin. The extra skin cells form scales and red patches that are itchy and sometimes painful. Psoriasis is a chronic disease that often comes and goes with no curative treatment. The main goal of current treatment is to offer symptoms relief and extend the relapse free duration. According to Frost & Sullivan, the prevalence of psoriasis in China increased from 6.5 million in 2017 to 6.7 million in 2021, representing a CAGR of 0.5%, and is expected to reach 6.8 million in 2025, representing a CAGR of 0.4% from 2021 to 2025 and 6.9 million in 2030, representing a CAGR of 0.2% from 2025 to 2030, suggesting a large market size in China.

#### Acquisition and Post-acquisition R&D activities

Before acquisition in June 2020, CU-10401 was in pre-clinical studies. Wuhan Yingnashi Pharmaceutical Co., Ltd. (武漢英納氏藥業有限公司) has not initiated any clinical trials of CU-10401 globally. After acquisition, we conducted analysis from pre-clinical, CMC and prepared research and development plan. We have devoted considerable amount of time and resources to the R&D work of CU-10401, which includes, among others, developing formulation and domestic manufacture process.

#### Competitive Advantages

The active ingredient of CU-10401, tapinarof, is an AhR targeted drug with mechanism of action involving immune modulation, skin-barrier normalization, and antioxidant activity. It is a non-steroidal small molecule chemical drug and carries a lower risk of adverse effects than topical corticosteroid or other systemic therapies. It has the potential to become a topical therapy with combined advantage in efficacy, safety, and treatment convenience. Compared with calcipotriol, another commonly used topical nonsteroidal agent, CU-10401 demonstrated a lower relapse rate (7.3% vs 8.5%) according to Consensus on the Treatment of Psoriasis with Benvitimod Cream.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-10401 SUCCESSFULLY.

#### **TOPICAL ANESTHESIA**

Topical anesthesia offer better patient comfort and eliminate the needle use as well as the associated pain and risk of conventional local anesthesia, such as infection and distortion of wound and systemic absorption of anesthetics, demonstrating the potential for broad application in clinical use. Currently, only two topical anesthetics compound chemical products for puncture and superficial dermatological procedures are approved in China and both of them are compounds of lidocaine and prilocaine. Existing compounded lidocaine and prilocaine topical anesthetics need plastic occlusion and have slow onset and short duration of action, which is not optimal for clinical use.

CU-30101 is a localized lidocaine and tetracaine compound topical anesthesia cream. We acquired in November 2019 all the intellectual property and ownership of CU-30101 in Greater China, consisting Mainland China, Hong Kong, Macao and Taiwan, from Sparkmed Research LLC, a biotech company in the U.S. Compounded lidocaine and prilocaine formula is currently the only marketed topical compounded anesthesia cream in China but has shortcomings such as slow onset, and unsatisfactory anesthetic strength. CU-30101's lidocaine and tetracaine combination formulations produce rapid and long-lasting anesthetic effects due to its ingredients' unique pharmacokinetic properties. Lidocaine diffuses more rapidly, and more extensively than tetracaine, whereas tetracaine, a long-acting amino acid ester, is more lipophilic than lidocaine and can be concentrated in the topical stratum corneum. Systemic absorption of the anesthetic component ingredients is also limited from the topical cream

formulation. We filed IND application in August 2022 and received the NMPA approval for equivalence clinical trial for CU-30101 in November 2022. We also received the ethic approval for a randomized, multi-center, double-blind, positive drug control, pairing designed Phase III clinical trial to evaluate safety and efficacy for CU-30101 in January 2023, based on the NMPA approval. We plan to commence the Phase III clinical trial in the second quarter of 2023 and submit an NDA to the NMPA in 2025.

Before acquisition in November 2019, CU-30101 was a cream prototype and Sparkmed Research LLC provided its formula. Sparkmed Research LLC had not initiated any clinical trials of CU-30101 globally. After acquisition, we had conducted analysis from pre-clinical, CMC and clinical perspectives and prepared research and development plan. We submitted the IND application for a Phase I clinical trial of CU-30101 to the NMPA and obtained approval in November 2022. We have devoted considerable amount of time and resources to the R&D work of CU-30101, including, among others, that (i) we developed the current formulation and conducted a large-scale manufacturing process, (ii) we developed analytical procedures to control product quality, and (iii) after completing a 130kg batch stability study and pre-clinical studies, we submitted a clinical trial application to the NMPA and received approval.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-30101 SUCCESSFULLY.

#### **PRODUCTS FOR DISTRIBUTION**

#### **CUP-MNDE:** Commercialized OTC Minoxidil Spray

CUP-MNDE is a commercialized, over-the-counter minoxidil spray indicated for alopecia, including male patients with progressive thinning or losing hair on the apical area and female patients with overall fragile thinning hair. The active ingredient, minoxidil, is widely used and proven efficacious in clinical trials and clinical practice for male and female hair regrowth. CUP-MNDE is refreshing to be applied to the scalp as a result of its low concentration propylene glycol formulation, which is proven to have much fewer side effects associated with propylene glycol than the competitor minoxidil liquid. The key ingredient of CUP-MNDE is minoxidil, which can promote hair growth by relaxing the muscular walls of blood vessels, allowing blood, nutrients and oxygen to flow more easily to the scalp and hair follicles. CUP-MNDE has been commercialized by its original developer Laboratoires Bailleul in Europe and according to Frost & Sullivan, it is the best-selling minoxidil brand in terms of volume sold in Italy, Portugal and Belgium in 2021.

On June 1, 2021, we entered into a distribution agreement (the "CUP-MNDE Agreement") with Laboratoires Bailleul International S.A. ("Laboratoires Bailleul"). Pursuant to the CUP-MNDE Agreement, Laboratoires Bailleul grants to us individual, direct and exclusive distribution rights to develop the distribution and marketing of CUP-MNDE in Mainland China excluding Hong Kong, Macao and Taiwan. For more details, see "– Collaboration and Licensing Arrangements – CUP-MNDE Agreement". We commenced distribution of CUP-MNDE under the brand name Bailleul in January 2022. During the first

three years of the CUP-MNDE Agreement, we commit to minimum annual purchase volumes of 56,000, 158,000 and 259,000 units for the first, second and third year, respectively. As confirmed by Laboratoires Bailleul, we had met the minimum annual purchase targets for CUP-MNDE during the Track Record Period and up to the Latest Practicable Date. In the year ended December 31, 2022, we recorded total revenue of RMB9.2 million from sales of CUP-MNDE, 51.2% of which was derived from sales through the Tmall Global e-commerce platform. As of the Latest Practicable Date, there has not been any product recall of CUP-MNDE since entering into the CUP-MNDE Agreement.

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 as the contracting party directly sells CUP-MNDE and CUP-SFJH to customers through the Tmall Global e-commerce platform and sells another portion of CUP-MNDE through a distributor in Hong Kong, which then sells our products to a subdistributor, 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.

#### CUP-SFJH: Commercialized Hair Growth Serum

CUP-SFJH is a commercialized, hair growth serum featuring a non-hormonal formula of natural plant extracts. CUP-SFJH is used for hair loss prevention and hair quality improvement. With its unique liposome technology, CUP-SFJH can transport nutrients to the root of the hair follicles through the double-layer phospholipid membrane wrapping. CUP-SFJH can also be used in combination with our scalp disease drug products to maintain desired results and reduce side effects. We started commercialization of CUP-SFJH under the brand name ESTHECIN in August 2022. CUP-SFJH contains a combination of natural ingredients that are fully plant-based with each ingredient playing a different role in supporting the natural hair growth cycle.

On September 1, 2021, we entered into an agreement (the "**CUP-SFJH Agreement**") with Van Montfort Laboratories B.V. ("**VML**"). Pursuant to the CUP-SFJH Agreement, VML grants to us the direct and exclusive distribution rights within Mainland China excluding Hong Kong, Macao and Taiwan for CUP-SFJH. For more details, see "– Collaboration and Licensing Arrangements – CUP-SFJH Agreement". According to the CUP-SFJH Agreement, during the first three years of the CUP-SFJH Agreement, we commit to minimum annual volume of purchases of 20,000, 60,000 and 100,000 units in the first, second and third year, respectively.

We had met the minimum annual purchase targets for CUP-SFJH during the Track Record Period and up to the Latest Practicable Date. We did not record any sales of CUP-SFJH in 2021. Sales amount of CUP-SFJH was RMB37,000 in 2022. During the Track Record Period, all of the sales of CUP-SFJH was generated on Tmall Global e-commerce platform (Cutia HK as the contracting party). As of the Latest Practicable Date, there has not been any product recall of CUP-SFJH since entering into the CUP-SFJH Agreement.

#### 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 irrecocably 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.

#### 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 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 an agreement (the "**CU-40102 Agreement**") with Polichem S.A. ("**Polichem**"), a subsidiary of Almirall, S.A. (BME: ALM) ("**Almirall**"), an Independent Third Party and a global pharmaceutical company specializing in the research, development, manufacturing and marketing of pharmaceutical products. Its major focus is on skin-health pharmaceutical products with principal place of business in Barcelona, Spain.

As confirmed by Almirall, Polichem was the sole and exclusive owner of intellectual property rights, including patents, know-how and trademarks of CU-40102 globally. Pursuant to the CU-40102 Agreement, Polichem grants 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 androgenic alopecia in Greater China consisting of Mainland China, Taiwan, Hong Kong and Macao. Polichem has exclusive rights in the R&D, manufacturing and commercialization of CU-40102 outside Greater China. We can also sublicense the CU-40102 to our affiliates without Polichem's consent, or to third parties with Polichem's prior written consent.

Polichem will deliver to us the available documentation in its possession which is necessary for the purpose of obtaining the marketing authorization, price and reimbursement approval and other registrations, including data relating to chemical production of the API, in Greater China. As of the Latest Practicable Date, all such information, including know-how, had been granted to us. We will develop, obtain the marketing authorization and commercialize CU-40102 at our own costs and expenses and conduct the commercialization activities in Greater China. We have the right to obtain market authorization on be half of Polichem, and Polichem or its designee will be the holder of the marketing authorization in Greater China.

In consideration of the licenses and rights granted to us, the down payments and the maximum milestone payments payable by us amount to  $\leq 13.75$  million in the aggregate, which includes non-refundable down payments of  $\leq 5.25$  million and milestone payments of  $\leq 8.5$  million consisting of commercial milestone payments, including (1)  $\leq 0.5$  million when annual net sales first meets or exceeds  $\leq 25$  million; (2)  $\leq 1.5$  million when annual net sales first meets or exceeds  $\leq 50$  million; (3)  $\leq 2.5$  million when annual net sales first meets or exceeds  $\leq 75$  million, and (4)  $\leq 4.0$  million when annual net sales first meets or exceeds  $\leq 100$  million. We expect to pay the remaining non-refundable down payment upon the marketing authorization by NMPA and the successful first sales of the CU-40102. We are also obligated to pay royalties of 2% of annual net sales of CU-40102. As of the Latest Practicable Date, we had paid  $\leq 4$  million under the CU-40102 Agreement, which was part of our non-refundable down payments.

Unless earlier termination, the term for the CU-40102 Agreement is 15 years with automatic renewals. Polichem has the right to terminate the CU-40102 Agreement by serving written notice on us only upon the occurrence of breaches and which are not remedied within 90 calendar days including (a) if we have not received marketing authorization of CU-40102 in Greater China within five years following the filing of IND; (b) if we fail to launch the CU-40102 no later than six months after obtaining the marketing authorization; (c) if we fail to promote and/or sell the product for two consecutive calendar quarters; (d) if we fail to achieve the minimum sales for two consecutive marketing years, with a minimum annual

volume of purchases of 16.8, 56.8 and 124.8 thousand units in the first, second and third year after the commercial launch; or (e) certain insolvency events, including (i) filing of a petition in bankruptcy or insolvency, (ii) filing of any petition or answer seeking reorganization, readjustment, or rearrangement of the business of the other party or of any its affiliate under any law or any government regulation relating to bankruptcy or insolvency, (iii) appointment of a receiver for all or substantially all of the property, (iv) assignment or attempted assignment made for the benefit of creditors, or (v) institution of any proceedings for the liquidation or winding up of the business, or for the termination of the corporate charter. If the CU-40102 Agreement is extended, the minimum sales applicable for each calendar year after the marketing year. If both parties fail to reach an agreement regarding the minimum sales for a particular year, such minimum sales will be deemed to be 90% of the minimum sales applicable in the respective immediately preceding year. If we fail to achieve the applicable minimum sales for two consecutive marketing years, Polichem shall have the right to terminate the CU-40102 Agreement and claim any damages and losses caused.

We have the right to terminate the CU-40102 Agreement by written notice in case of certain insolvency events on the part of Polichem, including (i) filing of a petition in bankruptcy or insolvency, (ii) filing of any petition or answer seeking reorganization, readjustment, or rearrangement of the business of the other party or of any its affiliate under any law or any government regulation relating to bankruptcy or insolvency, (iii) appointment of a receiver for all or substantially all of the property, (iv) assignment or attempted assignment made for the benefit of creditors, or (v) institution of any proceedings for the liquidation or winding up of the business, or for the termination of the corporate charter.

#### 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 and a PRC company specializing in the R&D of pharmaceutical products. The CU-40101 Agreement became effective on May 1, 2020 and will expire 20 years from product launch.

Pursuant to the CU-40101 Agreement, TechnoDerma grants to us an exclusive, royaltybearing, and assignable license to develop, manufacture and commercialize CU-40101 in Asia for dermatology indication of hair growth (the "**CU-40101 Field**"). TechnoDerma has exclusive rights in the R&D, manufacturing and commercialization of CU-40101 outside Asia. 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. We will act as the sole owner of CU-40101 in the CU-40101 Field and in Asia for registration filing activities. If we wish to sublicense CU-40101 to a third party within the CU-40101 Field in Asia, we shall notify TechnoDerma in advance and TechnoDerma shall have the right of first refusal under the same conditions. Such sublicense must be approved by TechnoDerma in advance and the third party must continue to perform all rights and obligations under the terms of the CU-40101 Agreement, and we shall be jointly and severally liable for any breach by the third party.

In consideration of the licenses and rights transferred to us, we are required to pay an aggregate of RMB60.0 million, which includes non-refundable upfront fees of RMB15.0 million and development milestone payments of RMB45.0 million. Development milestone includes initiation of a Phase I clinical trial in China, completion of a Phase II clinical trial in Asia with favorable results or we decide to continue a subsequent clinical trial, and receiving marketing approval for the first time in Asia. 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.

An early termination of the CU-40101 Agreement can result from (i) a change of control and the other party gives such a party 10 days written notice to terminate the CU-40101 Agreement, including but not limited to, the change of our CEO that materially affects our R&D, manufacturing and commercialization of CU-40101 in Asia, (ii) 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, and (iii) either party breaches the CU-40101 Agreement and the breaching party fails to make restitution or cure within 10 days of receipt of such written notice or within a mutually agreed period of time.

#### **CU-10201** Agreement

On April 21, 2020, we entered into an agreement (the "**CU-10201 Agreement**") with Foamix, an Independent Third Party and a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical foams to address unmet needs in dermatology. Foamix has been conducting research, development, and commercialization of certain topical minocycline products. Its principal place of business located in Rehovot, Israel.

Pursuant to the CU-10201 Agreement, we are granted an exclusive, royalty-bearing license, 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 has exclusive rights in the R&D, manufacturing and commercialization of CU-10201 outside Greater China. We can also sublicense the CU-10201 to our affiliates without Foamix's consent, or to third parties with Foamix's prior written consent. Foamix is the marketing authorization holder and we are acting as agent of Foamix to fulfil Foamix' obligation. Foamix was a subsidiary of Menlo Therapeutics Inc. (Nasdaq: MNLO), whose corporate name was changed to VYNE Therapeutics Inc. (Nasdaq: VYNE) in late 2020. VYNE Therapeutics Inc. had assigned rights and obligations of Foamix under the CU-10201 Agreement to Journey Medical Corporation effective as of January 12, 2022.

As confirmed by Journey Medical Corporation, Foamix was the sole and exclusive intellectual property rights owner of CU-10201 globally. Pursuant to the CU-10201 Agreement, Foamix will provide us with Foamix know-how regarding CU-10201. Foamix and we will organize a joint development committee that will establish a reasonable process and schedule

for the transfer of any additional Foamix know-how that subsequently becomes controlled by Foamix or its affiliates. As of the Latest Practicable Date, all such know-how had been provided to us. We conduct all regulatory activities in connection with the development and commercialization of CU-10201 in Greater China. We shall obtain and maintain all regulatory approvals and other relevant regulatory materials necessary to manufacture CU-10201 in Greater China. After we hold regulatory approvals and other relevant regulatory materials necessary for the development and commercialization of CU-10201 in Greater China, we shall be solely responsible for all regulatory activities, including making additional regulatory materials and obtaining additional regulatory approvals for CU-10201 from the NMPA in Greater China.

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 CU-10201 by the NMPA. We are also obligated to pay royalties of 4% of annual net sales of CU-10201. As of the Latest Practicable Date, we had paid non-refundable US\$10.0 million under the CU-10201 Agreement.

Unless terminated earlier, the CU-10201 Agreement shall continue in full force and effect for 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. Foamix has the right to terminate the CU-10201 Agreement by serving written notice on us if we materially breach our obligations under the CU-10201 Agreement and after receiving written notice identifying such material breach in reasonable detail, we fail to cure such material breach within 60 days from the date of such notice, provided that, such cure period shall be extended for up to an additional 60 days upon providing a written plan that reasonably demonstrates the need for such additional time and continuing to cure such breach. We have the right to terminate the CU-10201 Agreement in its entirety (a) at any time for convenience upon 90 days' prior written notice given to Foamix, or (b) upon prior written notice given to Foamix, if a regulatory authority in Greater China including Mainland China, Taiwan, Hong Kong and Macao has ordered us to stop all sales of CU-10201 due to a safety concern; provided that we have, for a period of 90 days prior to the provision of such notice, used commercially reasonable efforts to resolve such safety concern. We also have the right to terminate the CU-10201 Agreement by serving written notice on Foamix if it materially breaches obligations under the CU-10201 Agreement and after receiving written notice identifying such material breach in reasonable detail, Foamix fails to cure such material breach within 60 days from the date of such notice, provided that, such cure period shall be extended for up to an additional 60 days upon providing a written plan that reasonably demonstrates the need for such additional time and continuing to cure such breach. In addition, either party may terminate the CU-10201 Agreement if the other party files in any court or agency pursuant to a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that party or of its assets, or if the other party proposes a written agreement of composition or extension of its debts, or if the other party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within 60 days after the filing thereof, or if the other party proposes or becomes a party to any dissolution or liquidation, or if the other party makes an assignment for the benefit of its creditors.

#### **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 and a pharmaceutical company specializing in the development and marketing of pharmaceutical products, food supplements and dermo-cosmetic products with principal place of business in Genève, Switzerland. Pursuant to the CUP-MNDE Agreement, Laboratoires Bailleul grants to us individual, direct and exclusive distribution rights to develop the distribution and marketing of 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.

Laboratoires Bailleul guarantees that all the products it delivers are in compliance with quality assurance specifications, that they are appropriate to the use for which they are sold. Any product not meeting the above conditions will be recalled from us at the expense of Laboratoires Bailleul. During the first three years of the CUP-MNDE Agreement, we commit to minimum annual purchase volumes of 56,000, 158,000 and 259,000 units for the first, second and third year, respectively. As confirmed by Laboratoires Bailleul, we had met the minimum annual purchase targets for CUP-MNDE during the Track Record Period and up to the Latest Practicable Date. We will carry out the promotion and sales of the products in accordance with the strategy validated by Laboratoires Bailleul. We promise to devote 20% of the pre-tax product sales to advertising and promotion. In the event that advertising and promotional expenses for any year were less than the percentage above, the shortfall must be expended in the course of the first quarter of the next year, with no impact on the advertising and promotional expenses which must be expended for next year. Under the CUP-MNDE Agreement, Laboratoires Bailleul is the market authorization holder, and we will obtain market authorization in the name and on behalf of Laboratoires Bailleul. We will be in charge of coordinating regulatory activities related to marketing, local distribution and all product sales and marketing activity, including but not limited to the coordination of regulatory noncompliance or complaints in China during the commercialization of CUP-MNDE.

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 from either party at least three months before the expiration date. The agreement will be terminated as of right by Laboratoires Bailleul or us and without prior notice or compensation in the event of receivership, compulsory liquidation or legal settlement with any third party, in compliance with current legal and regulatory conditions and with the observance of any conditions of a public nature which might apply. The CUP-MNDE Agreement can be terminated by Laboratoires Bailleul on the following conditions: (i) if we fail to meet the development plan objectives, which include minimum sales obligation, volume of purchases and marketing policy, and other obligations in all material aspects under the CUP-MNDE Agreement; (ii) if we fail to refrain from developing, registering, manufacturing,

distributing, promoting or marketing, directly or indirectly, any products benefitting from the technical information of Laboratoires Bailleul and refrain from manufacturing, selling, or promoting competing or similar products for CUP-MNDE; (iii) if Ms. Zhang Lele ceases to be our CEO; (iv) if we transfer all or the majority of the rights and obligations under this agreement without the express prior written agreement from Laboratoires Bailleul, or if we transfer our area of activity when fulfilling our contractual obligations without the express prior written agreement from Laboratoires Bailleul; or (v) if a change of more than 30% in the share-ownership or control in either of the parties occurs without the express prior written agreement of the other party. We have not received any notice from Laboratoires Bailleul regarding any breach of the contractual obligation during the Track Record Period and up to the Latest Practicable Date. Laboratoires Bailleul and we may revisit the terms of the agreement at the time of renewal of the CUP-MNDE Agreement.

#### **CUP-SFJH** Agreement

On September 1, 2021, we entered into an agreement (the "**CUP-SFJH Agreement**") with Van Montfort Laboratories B.V. ("**VML**"), an Independent Third Party and a company specialized in the research, production and marketing of cosmetic products with principal place of business in Maastricht, the Netherlands. 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 Mainland China during the term and in pursuit of the CUP-SFJH Agreement. VML is the market authorization holder of CUP-SFJH in Mainland China.

We should carry out the promotion and sales of CUP-SFJH. Once per year, we and VML will determine the commercialization and marketing policy and plan, including sales objectives, promotions and advertisements. We are also responsible for the regulatory non-compliance or complaints in China during the commercialization of CUP-SFJH.

In compensation for this exclusivity, we will purchase CUP-SFJH exclusively from VML and promise to develop the distribution and marketing of CUP-SFJH throughout Mainland China according to the marketing plans and investments to be proposed by us and validated yearly by VML. VML guarantees that the products are free from serious defects at the moment of delivery. Any product not meeting the conditions will be recalled from us at the expense of VML. During the first three years of the CUP-SFJH Agreement, we commit to a minimum annual volume of purchases of 20, 60 and 100 thousand units in the first, second and third year, respectively. We had met the minimum annual purchase targets for CUP-SFJH during the Track Record Period and up to the Latest Practicable Date.

The CUP-SFJH Agreement has an initial term beginning on September 1, 2021 and ending on December 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 of the period underway. If we fail to meet the minimum annual purchase volume during the period of a year, VML at its sole discretion will have the right to terminate the CUP-SFJH Agreement

unilaterally and attribute liability for the termination to us. In addition, VML has the right to terminate the CUP-SFJH Agreement or decide at its sole discretion to cancel, instead of terminating, the territorial exclusivity of this agreement, at the end of a period of 90 days from the date that the written notice was sent by registered letter with return receipt requested specifying the pertinent performance failures and/or breaches of contractual obligations. The CUP-SFJH Agreement will also be terminated without prior notice or compensation in the event of receivership, compulsory liquidation or legal settlement with any third party with current legal and regulatory conditions and with the observance of any conditions of a public nature which might apply. VML and we may revisit the terms of the agreement at the time of renewal of the CUP-SFJH Agreement.

#### **OUR PLATFORM**

We have established a platform including strong R&D capabilities, as well as manufacturing, regulatory affairs and commercialization capabilities targeted at dermatology industry. Our platform spans from the early phase of identifying demand, developing core technologies, managing clinical trials and product registrations, to the manufacturing and marketing of products. We believe that our integrated capabilities give us the agility to formulate our innovation, registration, commercialization and product optimization strategies that can navigate us through rapidly changing market needs, enabling us to improve pipeline viability and expedite product development cycle at lower costs. We believe that our proprietary CATAME<sup>®</sup> technology platform will continue to drive our technology innovation and product development.

#### **Research and Development**

We have developed our clinical and pre-clinical pipeline through a combination of self-development and licensing arrangements. As of the Latest Practicable Date, our R&D team consisted of approximately 32 employees. Our R&D members have an average of seven years' experience in R&D. Among our R&D team members, 18 members have obtained master degrees or doctorate degrees. Of those 18 members, six members of our R&D team are responsible for the development of the Core Product since the acquisition of the Core Product. Our R&D team is led by Dr. Lei Lei (雷磊博士), who is a senior specialist in pharmaceutical development. Dr. Lei has rich experience in the development of medical products at multinational pharmaceutical companies. He was the former principal scientist at Shanghai Johnson & Johnson Pharmaceuticals Ltd (上海強生製藥有限公司). Dr. Lei authored more than 20 international academic papers and is leading a Shanghai New Drug Support Fund Project. Our experienced in-house R&D team comes from a variety of medical backgrounds and has 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, quality control, 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.

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# BUSINESS

The following table summarizes information regarding the contributions of members of the Directors and the senior management, drug discovery team, CMC team and medical team individually and collectively which justify and demonstrate our R&D and commercialization capabilities to enable us to partner with third parties and to be assigned with rights and licensing arrangements of our product portfolio:

Responsible Members to	o the Acquisition/License.	<b>R&amp;D</b> and Commercialization
Responsible members of	o the negation/ Dicense	Red and commercialization

Products	Status	Contribution
CU-20401	Acquisition	Ms. Zhang Lele (張樂樂女士) works with Business Development team to manage the acquisition from Rejuven Dermaceutical Co., Ltd.
	Pre-clinical	Dr. Lei Lei (雷磊博士) from R&D team leads pharmacology studies. The R&D team is responsible for CMC, toxicology and PK/pharmacodynamics studies.
	Clinical	The regulatory affairs team is primarily responsible for regulatory communications, and Mr. Zhu Qi (朱 琦先生) is primarily responsible for working with the medical team and external parties (CROs) to conduct clinical trials.
CU-40102	License	Ms. Zhang Lele (張樂樂女士) works with Business Development team to manage the license from Polichem S.A.
	Pre-clinical	Dr. Lei Lei (雷磊博士) and the R&D team are responsible for CMC, toxicology and PK/pharmacodynamics studies.
	Clinical	The regulatory affairs team is primarily responsible for regulatory communications, and Mr. Zhu Qi (朱 琦先生) is primarily responsible for working with the medical team and external parties (CROs) to conduct clinical trials.
	Commercialization	Ms. Zhang Lele (張樂樂女士) works with sales team to manage the sales network and formulate commercialization strategies.

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BUSINESS
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Products	Status	Contribution
CU-40101	License	Ms. Zhang Lele (張樂樂女士) works with Business Development team to manage the license from TechnoDerma Medicines Inc.
	Pre-clinical	Dr. Lei Lei (雷磊博士) from R&D team leads pharmacology studies. The R&D team is responsible for CMC, toxicology and PK/pharmacodynamics studies.
	Clinical	The regulatory affairs team is primarily responsible for regulatory communications, and Mr. Zhu Qi (朱 琦先生) is primarily responsible for working with the medical team and external parties (CROs) to conduct clinical trials.
CU-40103	Pre-clinical	Dr. Lei Lei (雷磊博士) from R&D team leads pharmacology studies. The R&D team is responsible for CMC, toxicology and PK/pharmacodynamics studies.
CU-40104	Pre-clinical	Dr. Lei Lei (雷磊博士) from R&D team leads pharmacology studies. The R&D team is responsible for CMC, toxicology and PK/pharmacodynamics studies.
CUP-MNDE	Commercialization	Ms. Zhang Lele (張樂樂女士) works with sales team to manage the sales network and formulate commercialization strategies.
CUP-SFJH	Commercialization	Ms. Zhang Lele (張樂樂女士) works with sales team to manage the sales network and formulate commercialization strategies.
CU-10201	License	Ms. Zhang Lele (張樂樂女士) works with Business Development team to manage the license from Foamix Pharmaceuticals Ltd.
	Pre-clinical	Dr. Lei Lei (雷磊博士) and the R&D team are responsible for project management, CMC, toxicology and DMPK studies.

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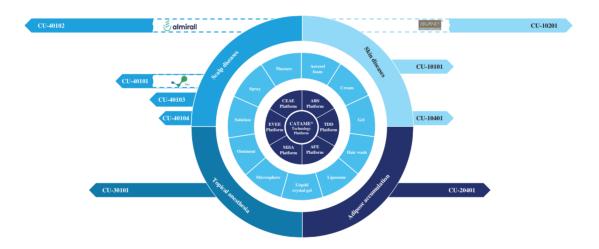
# BUSINESS

Products	Status	Contribution
	Clinical	The regulatory affairs team is primarily responsible for regulatory communications, and Mr. Zhu Qi (朱 琦先生) is primarily responsible for working with the medical team and external parties (CROs) to conduct clinical trials.
	Commercialization	Ms. Zhang Lele (張樂樂女士) works with sales team to manage the sales network and formulate commercialization strategies.
CU-10101	License	Ms. Zhang Lele (張樂樂女士) works with Business Development team to manage the license from Wuhan Yingnashi Pharmaceutical Co., Ltd.
	Pre-clinical	Dr. Lei Lei (雷磊博士) from R&D team leads pharmacology studies. The R&D team is responsible for project management, CMC, toxicology and DMPK studies.
CU-10401	Acquisition	Ms. Zhang Lele (張樂樂女士) works with Business Development team to manage the acquisition from Wuhan Yingnashi Pharmaceutical Co., Ltd.
	Pre-clinical	Dr. Lei Lei (雷磊博士) from R&D team leads pharmacology studies. The R&D team is responsible for project management, CMC, toxicology and DMPK studies.
CU-30101	Acquisition	Ms. Zhang Lele (張樂樂女士) works with Business Development team to manage the acquisition from Sparkmed Research, LLC.
	Pre-clinical	Dr. Lei Lei (雷磊博士) from R&D team leads pharmacology studies. The R&D team is responsible for project management, CMC, toxicology and DMPK studies.
	Clinical	The regulatory affairs team is primarily responsible for regulatory communications, and Mr. Zhu Qi (朱 琦先生) is primarily responsible for working with the medical team and external parties (CROs) to conduct clinical trials.

# CATAME<sup>®</sup> Technology Platform

The CATAME<sup>®</sup> technology platform is our in-house R&D platform comprising of six individual modules that enable capabilities that are critical for the drug development for different types of dermatological diseases: 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 & Efficacy Evaluation (EVEE) platform. Our CATAME<sup>®</sup> 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<sup>®</sup> technology platform enables the development of a wide range of product dosage forms and the relevant formulation technology as shown in the chart below. Through the platform, we have built a competitive product pipeline of creams, sprays, ointments, aerosol foams and other dosage forms.

The following chart summarizes the CATAME® technology platform:



- *Colloidal-Emulsification-Active Encapsulation (CEAE) Platform.* We formulate active ingredients into suitable topical formulations on our CEAE platform.
- *Aerosol (ARS) Platform.* We develop aerosol foams for broader dermatology treatment through our ARS platform.
- *Transdermal Delivery (TDD) Platform.* We research and analyze the transdermal delivery characteristics of our active pharmaceutical ingredients in the formulation through our TDD platform.
- Actives & Formulation Evaluation (AFE) Platform. We evaluate the quality, stability as well as physicochemical properties of our formulations through our AFE platform. Equipped with a series of equipments, we are able to conduct analysis and testing for various products on multiple physicochemical indicators.

- *Micro/Nano-Particulates & Self-Assembly (MiSA) Platform.* We develop our micron and nano-sized particulars through our MiSA platform.
- *Ex vivo & Efficacy Evaluation (EVEE) Platform.* We evaluate coverage of our product on *ex vivo* or *in vivo* tissues on our EVEE platform. In addition, through the platform, we can also evaluate the physiological changes, such as elasticity, thickness and density, of the skin tissues after product administration.

Once the patient or customer needs are identified, we will propose a technical solution based on the capabilities of our CATAME<sup>®</sup> platform, including but not limited to product formulation and/or product evaluation methods. We will then develop or evaluate the product candidate using the equipment, instruments and technologies available from our CATAME® platform. We believe the advantages of our CATAME<sup>®</sup> platform include that (i) the platform has a set of devices, instruments and technologies in each component including CEAE, ARS, TDD, AFE, MISA and EVEE to fulfill the entire function of the CATAME<sup>®</sup> platform, which provide technological support in the development of dermatology products. We have developed a range of topical dosage forms, from creams, ointments, tinctures to aerosols, all of which are useful in the management of different skin diseases. This allows us to develop more dermatology products than our peers to address a broad range of dermatology issues, as few companies have the capabilities to cover such a full range of topical dosage forms; (ii) with its formulation technologies, the platform allows us to differentiate our products with scientifically improved formulations; and (iii) the platform helps develop micron and nano-sized particulates, design the most suitable product formats that are key to specific and successful drug delivery, and evaluate formulation quality and stability, and cutaneous pharmacokinetic analysis. Based on the CATAME® technology platform, we have also successfully provided customers a product pipeline consisting of multiple candidates in various dosage forms.

We use our CATAME<sup>®</sup> platform to conduct R&D for our products, such as CU-20401, CU-40102, CU-40101, CU-40103, CU-40104, CU-10201, CU-10101, CU-10401 and CU-30101. Our CATAME<sup>®</sup> platform has competitive advantage compared with other similar platforms because all the six components of CATAME<sup>®</sup> are dedicated to topical skin formulations with specific functions for each platform. The "CEAE" platform is used for development of skin emulsifiers, the "MiSA" platform is for development of micro-nanoparticles, and the "TDD" and the "EVEE" platforms are for evaluation of transdermal behavior and skin efficacy. Thus, equipped with the CATAME<sup>®</sup> platform, we operate the six components sequentially or simultaneously to develop our products of a wider range of product dosage forms with a wider range of features to meet the needs of different skin diseases, compared with other competitive platforms that does not have comparable full range of CATAME<sup>®</sup> platform features. For example, we first use CEAE, ARS and MiSA platforms to prepare suitable formulations, then use TDD platform to analyze transdermal delivery, and use AFE and EVEE platforms to evaluate properties of the formulations.

In particular, although CU-10101 was originally in-licensed, the major development of the drug formulation was carried out internally by us using the CATAME<sup>®</sup> platform. During the development of CU-10101, we proposed a technical solution of using a topical ointment as a dosage form and incorporating up to 3% weight by weight of the active compound. The CEAE platform allowed us to screen for the most suitable excipients that could bind and solubilize large amounts of CU-10101 and remain compatible with each other. The CU-10101 formulation can carry up to 3% of the compound and successfully maintain drug delivery for nearly 24 hours, a time period that is scientifically desirable for a once-daily application of an atopic dermatitis product. By using the AFE platform, we can effectively evaluate our formulations on multiple physiochemical indicators including stability and quality, which enabled us to identify a preferred antioxidant to add to the formulation to protect the active substance from light. Therefore, by using the CATAME<sup>®</sup> platform, we optimized the formulation for successful drug delivery and developed an ointment formulation suitable for CU-10101, providing greater value to CU-10101. Moreover, we have filed two PCT patent applications in connection with CU-10101 arising from CATAME<sup>®</sup> technology platform, namely Hydroxydiphenylethylene Class Compound Ointment and the Use and Preparation Method Thereof and Hydroxystilbene Class Compound Ointment and the Use and Preparation Method Thereof. For more details, please see "- Intellectual Property" in this section.

Even though our Core Product CU-20401 is a subcutaneous injection, our CATAME<sup>®</sup> platform also contributes to its development. For example, the AFE platform is used to evaluate the quality, stability and physicochemical properties of the formulations. By using high phase liquid chromatograph of the AFE platform, we analyzed and improved the CU-20401 formulations.

### Drug Discovery and Pre-clinical Development

During the drug discovery stage, our R&D team focuses on exploring the activities of new chemical entities with disease targets, based on a thorough biological understanding of the disease. Our 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) screening and validation of compound with specific biological targets; (ii) analytical technology formulation and toxicology; and (iii) supporting systems including intellectual properties and quality assurance.

Our R&D team includes a drug discovery team and a CMC team. Our drug discovery team collaborates with our CMC team at an early stage to complement each team's needs and to ensure continued knowledge sharing, regulatory compliance and a streamlined transition from discovery to development.

Below are some of the highlights of our drug discovery and pre-clinical development capacities:

• Leveraging our CATAME<sup>®</sup> technology platform and our cooperation with CROs, we conduct extensive screenings to identify novel products.

- We conduct extensive *in vitro* screening of our molecules and to evaluate the activities of our drug candidates against disease targets and/or against efficacy-indicating cell models.
- After a product candidate shows the desired activities and meets all the other criteria for a pre-clinical candidate, we will move the candidate into CMC and pre-IND studies. Our drug candidates will be manufactured by our CMC team in collaboration with our CDMO partners. PK and long-term toxicity studies will be conducted in animals before filing for IND.

### **Clinical Development**

Our medical team is generally responsible for the clinical R&D works of our Core Product and other pipeline products. For our internally discovered and developed product candidates, we conducted clinical activities including: (i) coordinating all clinical development activities; (ii) designing the key aspects of the clinical study; (iii) designing and coordinating the selection process for qualified CROs to assist in engaging clinical sites and coordinating clinical studies once commenced; (iv) supervising the clinical studies; and (v) overseeing extensive regulatory outreach in China. For our acquired or in-licensed products, we are responsible for developing the candidates in our granted territories. We commenced research and development activities after acquiring or in-licensing product candidates from our partners. We have devoted a considerable amount of time and resources to the R&D of acquired or in-licensed product candidates, and such efforts include but are not limited to: (i) the design of the clinical trials to be implemented in our granted territories and proactive communication with relevant regulatory authorities to obtain the approvals; (ii) the preparation of clinical trials, including the selection of clinical CROs and clinical sites; and (iii) the manufacturing of clinical samples through our cooperation with CDMOs. Our drug discovery and pre-clinical R&D, clinical development, CMC and regulatory affairs teams have been working on the development of our products or product candidates during the post-acquisition or postlicensing period.

## Medical Team

Our medical team is led by our chief medical officer Mr. Zhu Qi. As of the Latest Practicable Date, our medical team consisted of 23 employees. Our medical team members have average of 11 years' clinical trial-related experience. Among our medical team members, approximately 52.2% have obtained post-graduate degrees from national and international reputed universities. Our medical team has experience in management of all stages of our clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. Our medical team covers most of the key functions in the drug development process, from clinical development strategy, clinical development planning, setting up quality assurance and control system, to clinical trial design, clinical trial management, safety monitoring, data management, data analysis and programming, clinical supply, procurement.

### Clinical Trial Design and Implementation

We have a dedicated medical team responsible for management of the clinical trials of our pipeline products. Our clinical trial personnel are responsible for the formulation of clinical trial design with CROs, selection of qualified clinical trial sites and monitoring of clinical trials to ensure that clinical trials comply with our protocols and the GCP standard.

During the Track Record Period, we cooperated with a number of PIs to conduct the clinical trials of our product candidates. To the best of our knowledge, none of them have any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates. The PIs are responsible for conducting site-level clinical research activities according to our trial protocols and in accordance with laws, regulations, and the GCP Guideline, a quality standard for the overall conduct of the clinical trial. Each trial has a leading PI with primary responsibility to ensure compliance with trial protocol and good clinical practice over the entire trial. Through the trial process and with the assistance of CROs, we closely monitor the trial activities, perform site audits, conduct an ongoing risk assessment and safety evaluation, review protocol deviated cases, and review clinical data to protect the safety of subjects and ensure the integrity of trial results. We collect and analyze trial data to prepare documentation for regulatory approvals of our product candidates.

### Collaboration with CROs

We collaborate with CROs (including SMOs) to conduct and support our pre-clinical and clinical studies in line with industry practice. We select our CROs by weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. To the best of our Company's knowledge, none of them have any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates.

In terms of the involvement and contributions of each of the major CROs to the development of our product candidates, the pre-clinical CROs mainly provide us with services related to pre-clinical toxicity and safety evaluations, such as animal studies, of our product candidates in accordance with our study design and under our supervision. The clinical CROs provide us with an array of services necessary for complex clinical trials in accordance with our trial design and under our supervision. CROs generally provide a comprehensive suite of services to assist us in implementing and managing clinical trials, including trial preparation, source data verification, clinical safety management, data management, and report preparation. We choose to engage a CRO based on the complexity and workload of a specific trial. We closely monitor the work of our CROs and provide specific directions to ensure the quality and efficiency of the trial execution. This approach allows us to leverage the experience of our in-house team to better focus on critical clinical trial elements, such as trial design, data analysis and decision making. All studies of our product candidates on humans are conducted in compliance with the applicable laws, regulations and in line with the industry standards. We believe our ability to conduct and work closely with CROs to conduct pre-clinical studies and clinical trials helps us to shorten the time required for product development as well as generate the requisite data in an reliable and efficient way.

We mainly determine the service fees paid to the CRO in accordance with then prevailing market prices of similar services, the number of enrolled patients, the duration of the clinical trials, and the quality and contents of the services provided.

### Manufacturing

### Manufacturing Facilities

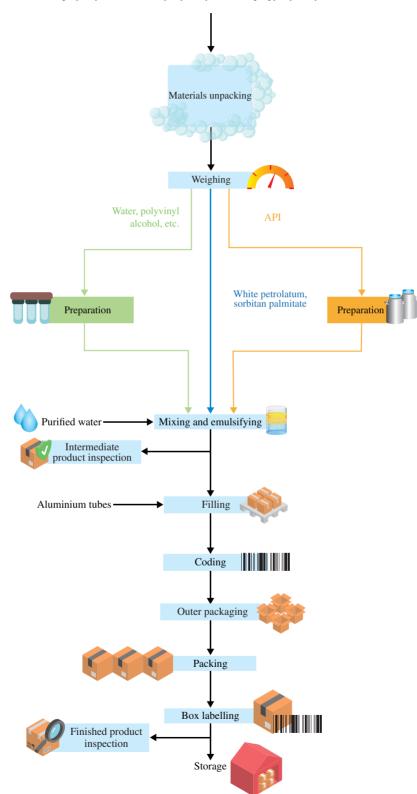
The construction of a commercial-scale GMP manufacturing facilities with three drug product production lines in Jiangsu province was completed in February 2023. The manufacturing facilities are equipped with three production lines covering cream, ointment, aerosol, and foam products with a planned annual production capacity of approximately a total of five million doses of CU-10101, CU-40103, CU-40104, CU-10401 and CU-30101. The site is expected to commence operation in the first quarter of 2023. We believe that upon completion the production capacity of this factory can support our clinical trials and near-term commercialization plans for our drug candidates. The flow and control of the entire manufacturing process are designed to be compliant with the latest cGMP requirements so that our production can meet the clinical and marketing approval requirements of various drug regulatory authorities, including the NMPA, FDA and European Medicines Agency.

As of the Latest Practicable Date, our manufacturing and quality control team consisted of 32 members, approximately 18.8% have obtained post-graduate degrees. Our manufacturing and quality control team has experience in process development, production and quality management and offers preclinical and clinical support throughout the drug development process. Our manufacturing and quality control team plays a critical role in drug development. It is responsible for developing safe, robust, and economically sound production processes for our drug substances and drug products, and ensuring their qualities meet regulatory requirements. We believe that we process the manufacturing capabilities and expertise in operating our own production facilities.

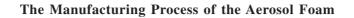
As our Wuxi plant is equipped to cover the production of creams and aerosols, our in-house production in these dosage forms will offer more overall advantages than engaging CDMO, such as lower manufacturing operating costs, agile and rapid response to facilitate product development and production progress, and reduced R&D expenses. For other product dosage forms that cannot be produced at this stage in our Wuxi plant, we engage CDMO for shared production facilities, reduced investment in fixed assets, and reduced R&D and conversion time.

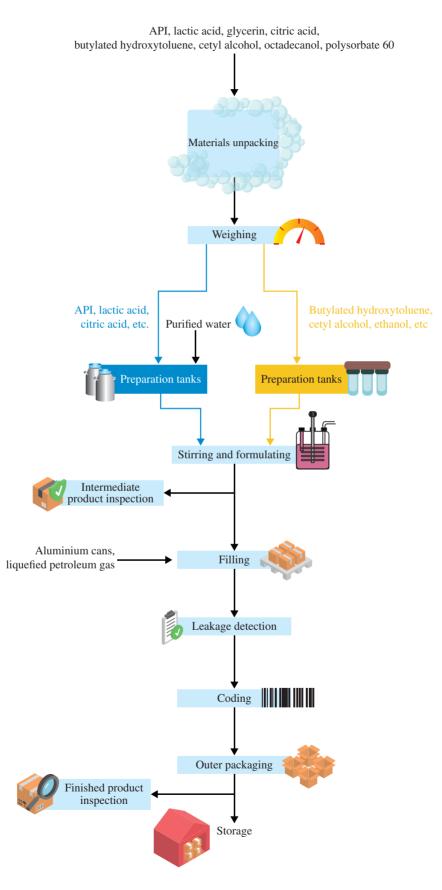
The flowchart below illustrates the designed manufacturing process of our products:

#### The Manufacturing Process of the Ointment Form



Water, white petrolatum, API, anhydrous calcium hydrogen phosphate, sorbitan palmitate, polyvinyl alcohol, methyl hydroxybenzoate, propyl hydroxybenzoate





#### Collaboration with CDMO partners

In terms of the involvement and contributions of each of the major CDMO partners (including CMOs) to the development of our product candidates, we collaborate with our CDMO partners to manufacture a portion of our product candidates to supply for pre-clinical studies and clinical trials. We did not experience any product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period.

Under our agreement with our CDMO partners, the CDMO partners are required to perform its services according to the prescribed time frame as set out in the agreement. Usually, we pay the CDMO partners in installments, with a specified credit period. Our CDMO partners are responsible for manufacturing our required products in accordance with certain product specifications, in compliance with cGMP requirements (where applicable), our quality standards and other applicable laws and regulations. We retain all the intellectual property rights and grant our CDMO partners the right to use our intellectual property rights for such manufacturing and packaging activities during the contract period. We are entitled to inspect and audit our CDMO partner's manufacturing process.

We mainly determine the service fees paid to the CDMO in accordance with then prevailing market prices of similar services, the duration of the clinical trials, the number of products manufactured, and the quality and contents of the services provided.

We maintained cooperation relationship with 27 and 39 CRO and CDMO partners in 2021 and 2022, respectively. For 2021 and 2022, the expenses attributable to CRO and CDMO partners were RMB43.3 million and RMB51.3 million, with RMB8.3 million and RMB12.1 million of such expenses attributable to research and development of our Core Product CU-20401, RMB18.1 million and RMB18.6 million of such expenses attributable to research and development of our Key Product CU-10201, RMB6.2 million and RMB16.7 million of such expenses attributable to research and development of our Key Product CU-40102. The following table sets forth background and expenses (exclusive of tax) of the CRO and CDMO partners engaged by us during the Track Record Period:

		Year e December	
Costs attributable to each major CRO/CDMO partners	Background and Contribution	Expenses	Percentage of total third party contracting expenses
		(RMB'000 percent	1
Parexel China Co. Ltd.	CRO based in China, providing clinical trial services, assisted us in implementing and managing clinical trials	13,870	32.0%

		Year ended December 31, 2021		
Costs attributable to each major CRO/CDMO partners	Background and Contribution	Expenses	Percentage of total third party contracting expenses	
		(RMB'00 percen	-	
Bestudy (Shanghai) Medical Technology Co., Ltd.	CRO based in China, providing clinical trial services, assisted us in implementing and managing clinical trials	7,343	16.9%	
Hangzhou Tigermed Consulting Co., Ltd.	CRO based in China, providing pre-clinical services related to pre-clinical toxicity and safety evaluations, and clinical trial services, assisted us in implementing and managing clinical trials	5,880	13.6%	
Clinical Service Center Co., Ltd.	CRO based in China, providing clinical trial services, assisted us in implementing and managing clinical trials	3,116	7.2%	
Wuhan Guanggu Humanwell Biological Pharmaceutical Co. Ltd.	CDMO based in China, providing development and manufacturing service of drugs	2,638	6.1%	
Total		32,847	75.8%	

		Year I December	
Costs attributable to each major CRO/CDMO partners	Background and Contribution	Expenses	Percentage of total third party contracting expenses
		(RMB'00) percen	
Hangzhou Tigermed Consulting Co., Ltd.	CRO based in China, providing pre-clinical services related to pre-clinical toxicity and safety evaluations, and clinical trial services, assisted us in implementing and managing clinical trials	14,232	27.7%
Parexel China Co. Ltd.	CRO based in China, providing clinical trial services, assisted us in implementing and managing clinical trials	14,022	27.3%
Clinical Service Center Co., Ltd.	CRO based in China, providing clinical trial services, assisted us in implementing and managing clinical trials	8,066	15.7%
Jiangsu Yaohai Bio- pharmaceutical Co., Ltd.	CDMO based in China, providing development and manufacturing service of drugs	2,294	4.5%
dMed Biopharmaceutical Co., Ltd.	CRO based in China, providing clinical trial services, assisted us in implementing and managing clinical trials	1,978	3.9%
Total		40,592	79.1%

#### **Quality Assurance and Control**

Quality control and assurance are crucial to us, and we endeavor to ensure the quality of our operations through a comprehensive quality management system, which was formulated in accordance with cGMP regulations and ICH Q10 guidance covering substantially every aspect of our operations including product R&D, procurement and manufacturing, among other things.

We have established a comprehensive set of quality control and assurance procedures to monitor our operations to ensure compliance with relevant regulatory requirements and our internal quality requirements. For example, we select our suppliers based on a strict set of criteria and regularly conduct supplier audits which include documentation inspection and/or on-site inspection on such qualified suppliers to make sure our requirements are being consistently met. We conduct inspection on raw materials in accordance with our quality management standards.

### **Regulatory Affairs**

As of the Latest Practicable Date, the regulatory affairs team consisted of eight professionals with an average of 14 years' experience in regulatory affairs. Our regulatory affairs team has experience in drug candidate registration as well as communication with regulatory authorities. 25% of team members have obtained post-graduate degrees. Our regulatory affairs team manages the regulatory submission process for our product candidates, which requires filings to be made to and approved by the relevant authorities before clinical trials and commercialization can be initiated. Our regulatory affairs team is responsible for the regulatory approval process including assembling application dossiers for IND and NDA, addressing inquiries from relevant authorities, conducting CMC and GMP compliance assessments for product candidates to ensure their compliance with relevant regulations. We possess rich knowledge and experience with regard to regulatory filings in China.

### OUR SALES, DISTRIBUTION AND MARKETING

### **Commercialization Strategy**

We plan to employ a strategic academic-promotion model to promote and sell CU-20401. Under this model, we expect to promote CU-20401 to hospitals and physicians in Greater China through academic marketing, establishing centers of excellence and referral network, and providing trainings to physicians.

After CU-20401 is approved by the NMPA, we plan to use and manage CU-20401 as a prescribed drug for adipose accumulation disease within specific use in the label approved by the NMPA. We currently plan to commercialize CU-20401 only in hospitals, focusing on the ones that are reputable and have served as clinical trial sites. We expect to only promote to hospitals and train registered physicians and distribute CU-20401 as a drug which is administered by registered physicians.

As the CU-20401 therapy is expected to be a new treatment process that is unlike any other treatment currently approved in China, we expect that significant efforts will be necessary to educate physicians and patients on the potential benefits of the CU-20401 therapy and prevent off-label use, and to demonstrate the proper process in administering and monitoring the treatment (including timely and proportionate measures to mitigate adverse effects).

We plan to build a focused in-house sales and marketing team to market CU-20401 across China. Our initial target is to establish a sales team of approximately 30 people to cover approximately 20 of the top hospitals in China with leading dermatology centers that are equipped with qualified and licensed physicians to administer our CU-20401 therapy. In particular, we plan to set up sales and operations teams at the target hospitals to facilitate the use of our products. These teams will strive to ensure our CU-20401 therapy is administered in accordance with the applicable standards and provide support to the licensed medical practitioners on site. For hospitals that have acted as clinical trial centers for CU-20401 while

it was under clinical stages, we believe the physicians involved may already have a chance to familiarize themselves with CU-20401. As our business grows over the next three years, we anticipate to expand our sales force to approximately 200 people in order to support the administration of our CU-20401 therapy at the top 100 hospitals in China.

As physicians are expected to play a key role in this process, not only in administering CU-20401 but also in educating patients about its potential benefits, we intend to design our marketing and academic education strategy around close and continued engagement with physicians. We believe that we have already established a rapport with some physicians across China through the clinical trials that we have conducted, in terms of both gaining recognition of the efficacy and potential benefits of CU-20401 and enhancing physicians' familiarity with the product candidate. In addition, we plan to be pro-actively involved in the policy making framework relating to the CU-20401 therapy by actively participating in consultation sessions with the relevant authorities, particularly on improving medical procedures and standards.

We plan to enhance our existing collaboration with these physicians through the establishment of a specialized team for medical affairs, which will oversee the training and support that we provide to physicians. In addition, we plan to develop a specialized, standardized training plan that will allow us to onboard and train physicians and treatment centers that have not been involved in our clinical trials, with the ultimate goal of gaining widespread acceptance of CU-20401 across the medical community and the general public.

The NMPA and other regulatory authorities strictly regulate the marketing, labelling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. 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 significant liability. In addition to the national regulation, we aim to adopt the following measures to prevent off-label use of CU-20401: (i) educating the physicians that CU-20401 is indicated for obesity or adipose accumulation, and accordingly shall only be prescribed for such indications. Physicians should prescribe medications only for NMPA-approved indications; (ii) providing one-month trainings to educate the physicians before administration of CU-20401, and provide a list of contents that they should avoid using in prescription activities to ensure compliance with relevant legal requirement; (iii) maintaining close communication with KOLs and clinical experts with the aim to ensure the proper administration and prescription of CU-20401, and implementing 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.

For other products, we operate an integrated commercialization model and we implement our marketing strategy primarily through online and offline channels. Other than CU-20401, we plan to sell substantially all of our products, including but not limited to CU-40102 and CU-10201 upon their respective approvals for commercialization, through online and offline channels in China. As of the Latest Practicable Date, we had not formulated the specific plan for our products in overseas market.

### **Online** Channel

Online marketing has always been one of our strategic priorities. We have a dedicated marketing team with strong market insights focusing on the development of marketing campaigns on various e-commerce platforms and social media platforms such as Tmall, Douyin, Zhihu and Xiaohongshu. Our comprehensive online marketing campaign strategy typically consists of several key steps, including raising brand awareness through increasing exposure on top media, product recommendation, distribution of news feed ads on emerging media platforms, introducing traffic to e-commerce platforms displaying and selling our products, live streaming promotion and experience sharing. We intend to make investments in online content platforms to formulate targeted marketing strategies for our products and conduct online and offline promotion events and activities.

We collaborated with MCNs that represent or collaborate with the KOLs with whom we work to further promote our products online through live streaming sessions and social media platforms. The duration of the agreement with the MCNs typically less than 12 months. We are entitled to confirm the date and time of each live streaming session before each live streaming session. The agreement usually specifies the products to be promoted through the live streaming session, the KOL who will conduct the live streaming session, the retail price and the extent of discounts offered during each live streaming session and the commission rate and the amount of fixed service fees of the MCNs. We regularly monitor the publicity of KOLs engaged by us and may negotiate with the relevant MCNs to replace any KOL who is found with deterioration of image or misconduct, including, but not limited to, inappropriate speech, unethical behavior or offense against the relevant laws and regulations. To our best knowledge and available public information, none of the KOLs we collaborated with had been under regulatory scrutiny and were suspended from KOL activities.

### **Offline** Channel

Our offline channel is an important bridge for us to directly reach consumers nationwide. Our offline marketing targets medical institutions to reach distinct end customers. In particular our offline marketing efforts will be characterized by a strong emphasis on academic promotion, in order to promote and strengthen the awareness and recognition of our products and our brand among medical institutions. We plan to adopt a physician-targeted approach focused on direct and interactive communication with KOLs and PIs, who are renowned physicians and leading experts in our target therapeutic areas, as well as team heads and senior physicians in our target hospitals to promote the differentiating clinical aspects of our products.

### **Our Distribution Network**

We have established a duo-channel distribution network to reach our customers. Our distribution network includes direct sales and sales to distributors. Since we are a biotech company and our Core Product and Key Products are still under clinical development or pilot commercialization, our sales and distribution network is at its early stage of development, and may further evolve as our business expand and product portfolio develop. 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 substantially expand our sales network to mass market.

We directly sell our products, including CUP-MNDE, CUP-SFJH as well as certain skin care products, including facial masks, creams, toners, sprays, serums and gels ("Routine Skin Care Products") to customers through online channels, including the Tmall e-commerce platform. We generally allow our individual consumers to return or exchange our products in a condition suitable for a second sale within seven days from the delivery according to the relevant laws and regulations. During the Track Record Period, our revenue from direct sales was RMB1,657,000, and RMB6,720,000 respectively, accounting for 81.3% and 59.1% of our total revenue for the same periods, respectively.

We have entered into distribution arrangements for CUP-MNDE and CUP-SFJH with the aim to (i) generate revenue to further support our R&D activities and daily operations; (ii) provide synergy with our existing and future products to expand our coverage and presence in the industry and (iii) increase our brand recognition to enhance cross selling among our product candidates. Although CUP-MNDE and CUP-SFJH are late entrants to the market, sales of CUP-MNDE and CUP-SFJH in 2022 amounted to RMB9.2 million in aggregate. Sales of CUP-MNDE amounted to RMB0.4 million in 2021, and we did not record any sales from CUP-SFJH in the same year. Our sales of CUP-MNDE and CUP-SFJH experienced significant growth for the past 12 months. As we anticipate there to be a continued strong market demand, we expect our sales of CUP-MNDE and CUP-SFJH to increase and will pursue our commercialization strategy in meeting such market demand.

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, as 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 as the contracting party directly sells CUP-MNDE and CUP-SFJH to customers through the Tmall Global e-commerce platform and sells another portion of CUP-MNDE through a distributor in Hong Kong, which 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 e-commerce 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.

If our commercialized products, including CUP-MNDE, CUP-SFJH and Routine Skin Care Products, which we distribute were to cause personal injury or injury to property, the injured party or parties could file a claim against us. We could also be subject to claims that consumers were harmed. We may have the right under contracts or applicable laws, rules and regulations to recover from the relevant brand partners or manufacturers compensation that we are required to make to consumers in connection with a product liability, personal injury or a similar claim. According to the E-Commerce Law of the PRC (《中華人民共和國電子商務 法》), the e-commerce platform would take responsibilities under the following situations: (i) where an e-commerce platform fails to take necessary measures when it knows or should know of the fact that operators on its platform sell commodities or offer services that fail to safeguard personal or property safety, or commit any other acts that impair the lawful rights and interests of consumers, the operator of such e-commerce platform shall be jointly held liable together with the violating operators on its platform; and (ii) where an e-commerce platform fails to fulfill its obligations to examine the qualifications of the operators on its platform which provide commodities or offer services having a bearing on consumers' life and health, or fails to fulfill its obligations to safeguard the safety of consumers, which results in damage to consumers, the operator of such e-commerce platform shall bear the corresponding liability. As advised by our PRC Legal Advisor, as to the cross-border e-commerce online sales, the obligation to ensure compliance with the E-Commerce Law primarily fall upon the e-commerce platforms. We cooperate with e-commerce platforms to comply with the related regulations. As to the sales of Routine Skin Care Products, as advised by our PRC Legal Advisor, we might be held liable under the E-commerce law as an e-commerce operator.

### Sales to Distributors

We sell CUP-MNDE, CU-40102, CU-10201 and Routine Skin Care Products to wholesale distributors. As of the Latest Practicable Date, we had five distributors, all of which are Independent Third Parties. To the best of our knowledge, during the Track Record Period and as of the Latest Practicable Date, none of our distributors is wholly owned or controlled by or has any past or present relationships or arrangements, including family relations, business, financing, guarantee and others, with our Company or our subsidiaries, their directors, shareholders, senior management or any of their respective associates, save for acting as a distributor of our products.

We sell CU-40102 and CU-10201 through a distributor in Hainan, which sells our products to a qualified medical institution in the Boao Pilot Zone for pilot commercialization. In addition to the direct sales of CUP-MNDE through Tmall Global e-commerce platform (Cutia HK as the contracting party), we sell another portion of CUP-MNDE through a distributor in Hong Kong, which sells our products to a sub-distributor, JD Health (京東健康) e-commerce platform. The JD Health (京東健康) e-commerce platform sells our products to individual customers. We sell our Routine Skin Care Products through three distributors in Mainland China, which sell our Routine Skin Care Products to customers through their offline stores or e-commerce platforms.

To the best of our knowledge, during the Track Record Period and as of the Latest Practicable Date, we did not receive any claims in relation to the distribution of our products. For details of our insurance policy, please refer to "– Insurance" in this section.

We believe this distribution model helps extend our coverage in a cost-effective manner while retaining proper control over our distribution network and sales and marketing process. Through our collaboration with established distributors, we believe we can increase market penetration in lower-tiered cities. During the Track Record Period, our revenue from our distribution network was derived from the revenue generated from our top five largest customers. The total revenue generated from our top five largest customers amounted to RMB381,000 and RMB4,646,000 in 2021 and 2022, respectively, accounting for 18.7% and 40.9% of our total revenue for the same periods, respectively.

### Our Distributorship Network

We believe that our distributors with strong sale channel management capabilities as well as sales and distribution experience of product candidates for broader dermatology treatment and care can help us penetrate a broader customers and consumers base and increase our market share as well as enhance our brand awareness efficiently. During the Track Record Period and up to the Latest Practicable Date, we had five distributors.

We typically enter into standard distribution agreements, which are sales and purchase agreements in nature, with our distributors with duration of up to three years. We generally do not have minimum purchase requirements, deposit and sales and performance targets to our distributors. The salient terms include contact term, pricing policy, payment and credit terms, logistics arrangement and warranty policies. We generally do not accept returns of products from sales to distributors, except for particular circumstances as agreed with the distributors, such as where the products have a shorter durability period than agreed and product quality defects. During the Track Record Period and up to the Latest Practicable Date, we did not record any products returned from our distributors.

### Distributors' Selection and Management

We select our distributors based on their experience and business performance in the broader dermatology treatment and care industry. During the Track Record Period, we had a total of five distributors and to the best knowledge of the Company, two of whom had engaged sub-distributor(s) for the distribution of our products. We did not impose any sales targets on our distributors during the Track Record Period.

We generally require and monitor our distributors to provide monthly checklists of their inventory status and sales activities. We require our distributors to have adequate storage conditions and facilities, a sufficient number of quality management personnel, and adequate sales channels resources. We adopt and implement distributor management policies which cover aspects including review of credit terms arrangement, regular review of the cooperation with the distributors and record-keeping.

We believe that our sales are driven by the actual consumer demand and therefore we are subject to minimal risk of channel stuffing in our distribution network, primarily because (i) we generally grant a short credit period to distributors; (ii) we only allow returns of products sold to distributors in certain circumstances; and (iii) we do not set minimum purchase requirements for distributors.

### Prevention of Cannibalization

In order to manage the risk of cannibalization of sales among our distributors, we have adopted the following measures:

- *Geographic restrictions*. For distribution of CUP-MNDE, CU-40102 and CU-10201, we specify the designated distribution area for which our distributors are responsible in our distribution agreements with them. The agreements also prohibit distributors from selling our products outside their respective designated distribution areas without our prior written consent.
- *Accountability policy*. For any action in breach of the distribution agreements, we may terminate the relevant distributors according to the terms of our distribution agreements with them.

• *End customer monitoring*. Our distributors focus on different distribution channels. The distributor in Hong Kong sells CUP-MNDE to JD Health (京東健康) e-commerce platform, and another distributor in Hainan sells CU-40102 and CU-10201 to a qualified medical institution in the Boao Pilot Zone for pilot commercialization. Three distributors in Mainland China sell Routine Skin Care Products via their offline stores or e-commerce platforms.

During the Track Record Period and up to the Latest Practicable Date, we were not aware of any material cannibalization or competition among our distributors within the same geographic area. Our Directors are of the view that the above measures are sufficient to mitigate potential cannibalization and competition among distributors.

#### Anti-corruption and Anti-bribery Measures

Our distributors are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations. During the Track Record Period and up to the Latest Practicable Date, we did not provide financing to any of our distributors except for credit terms we granted to them under the relevant distribution agreements. To the best of our knowledge, none of our employees and distributors was or has been the subject of, or otherwise involved in, complaints, investigations, or regulatory enquiries in relation to, any bribery or kickback arrangements during the Track Record Period and up to the Latest Practicable Date.

Due to management of our distributors and their inventory levels, our distributors did not materially breach our contract terms, and we did not have any material disputes with our distributors relating to the settlement of trade receivables during the Track Record Period and up to the Latest Practicable Date. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors, which could adversely affect our reputation, business operation or financial contribution.

### **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. In addition, our pricing strategies are also affected by the regulations and policies on the dermatological or pharmaceutical industry, including medical insurance reimbursement standards and regulation of medical and pricing practices.

For our Core Product, once the commercialization approval from NMPA has been obtained, we plan to formulate and adjust the pricing and commercialization strategy in order to market the product in Greater China. Our pricing and commercialization strategy will not benchmark the price of Kybella (an approved localized adipose accumulation management medication in U.S. and Europe indicated for improvement in the appearance of moderate to severe convexity or fullness associate with submental fat in adults) or the prices of the two Phase III pipeline candidates in China.

As of the Latest Practicable Date, we did not observe any material negative effect or material fluctuation in our operations or the selling prices of the scalp diseases and care products and skin diseases and care products we offer due to the new pricing mechanism. For more details of risks associated with our product pricing, see "Risk Factors – Risks Relating to Manufacturing and Commercialization of Our Product Candidates – Failure to execute effective pricing strategy due to the government guidance or fiercer market competition could harm our ability to increase sales and erode our financial profits" in this Document.

### National Reimbursement Drug List ("NRDL") and National Essential Drug List ("NEDL")

Currently, none of our commercialized products have been included into the NRDL or 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. Inclusion into the NRDL or NEDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion. While products included in the NRDL or NEDL are typically generic and essential products, many innovative products have been included in the NRDL or NEDL in the past. 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. We may seek alternatives such as commercial private insurance coverage of our Core Product 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 where we plan to market and sell CU-20401 to qualified medical institutions that hold the Medical Practice License.

### Two-Invoice System

Two-invoice system refers to the mechanism where only up to two invoices are issued along the chain of pharmaceutical product procurement, with one issued by the pharmaceutical manufacturer to the distributor, and the other issued by the distributor to the medical service providers. Compared with the pre-reform procurement model, the two-invoice system aims to eliminate multiple layers of distributors along the supply chain of pharmaceutical products and streamline the procurement process, thereby ensuring that the price of pharmaceutical products is reasonable and affordable for the public. The sales of our marketed products are also subject to the regulation of two-invoice system.

As advised by our PRC Legal Advisers, the two-invoice system is mainly applicable to the procurement of certain drugs and medical consumables by public hospitals as of the date of this document. According to the Two-Invoice System Notice and the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》), which was issued on January 24, 2017, the two-invoice system would be promoted in pilot provinces (or autonomous regions and municipalities directly under the central government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis. For further details, please refer to the paragraph headed "Regulatory Overview – Other PRC Regulations Relating to the Pharmaceutical Industry – Regulations on Two-invoice System" in this document. Our sales to the distributors are not subject to the requirements of two-invoice system. As advised by our PRC Legal Advisers are of the view that our current sales operations do not violate the two-invoice system.

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 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 the Company's PRC Legal Advisor, the laws and regulations governing PRC pharmaceutical operation, including regulations on two-invoice system, are not applicable to the Company's dealing of CUP-MNDE and CUP-SFJH, as 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. Besides, the two-invoice system is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-off basis. Because the two-invoice system is mainly applicable to the procurement of certain drugs and medical consumables by public hospitals, the PRC laws and regulations governing the two-invoice system shall not be applicable to sales of CUP-MNDE and CUP-SFJH. Thus, as advised by our PRC Legal Advisor, we are not exposed to any liability due to non-compliance of the relevant rules and regulations on two-invoice system.

The following table sets forth the details of our sales model for our commercialized products as of the Latest Practicable Date.

Products	Mode of Distribution	Distribution channels	Sales liability(ies) under the relevant mode of distribution	Analysis regarding the two- invoice system in the PRC
CU-40102	Sales to distributors	Third party distributor in Hainan which sells the products to a qualified medical institution in the Boao Pilot Zone	Medical institutions shall be responsible for the clinical use of urgently needed imported drugs in accordance with the law. If the patient's body is injured during clinical use, the medical institution shall be liable for compensation in accordance with the relevant state regulations. According to the relevant law, if the injury is caused by drugs, the medical institution shall first compensate, and then reach an agreement with us to recover the compensation. We may seek remedies from the manufacturer if the product are not meeting the conditions or not free from serious defects.	As the two-invoice system is mainly applicable to the procurement of certain drugs and medical consumables by public hospitals, our PRC Legal Advisor is of the view that our current sales operations do not violate the two-invoice system.
CU-10201	Sales to distributors	Third party distributor in Hainan which sells the products to a qualified medical institution in the Boao Pilot Zone	Medical institutions shall be responsible for the clinical use of urgently needed imported drugs in accordance with the law. If the patient's body is injured during clinical use, the medical institution shall be liable for compensation in accordance with the relevant state regulations. According to the relevant law, if the injury is caused by drugs, the medical institution shall first compensate, and then reach an agreement with us to recover the compensation. We may seek remedies from the manufacturer if the product are not meeting the conditions or	As the two-invoice system is mainly applicable to the procurement of certain drugs and medical consumables by public hospitals, our PRC Legal Advisor is of the view that our current sales operations do not violate the two-invoice system.

not free from serious defects.

Products	Mode of Distribution	Distribution channels	Sales liability(ies) under the relevant mode of distribution	Analysis regarding the two- invoice system in the PRC
CUP- MNDE	Direct sales	Tmall Global	As advised by our PRC Legal Advisor, as to the cross-border e-commerce online sales, the obligation to ensure compliance with the E-Commerce Law primarily fall upon the e-commerce platforms. We cooperate with e- commerce platforms to comply with the related regulations and may be liable under the Law of the People's Republic of China on the Protection of Consumer Rights and Interests when consumers whose lawful rights and interests are infringed upon in purchasing or using commodities. We may seek remedies from the manufacturer if the product are not meeting the conditions or not free from serious defects.	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.
	Sales to distributors	Third party distributor in Hong Kong which sells the products to a sub-distributor, JD Health, which then sells to individual customers.	We may be liable under the terms of the agreement we have entered with the distributor, which subject to defective products, warranty expiration, or product recall issue.	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.
CUP- SFJH	Direct sales	Tmall Global	As advised by our PRC Legal Advisor, as to the cross-border e-commerce online sales, the obligation to ensure compliance with the E-Commerce Law primarily fall upon the e-commerce platforms. We cooperate with e-commerce platforms to comply with the related regulations. We may be liable under the Law of the People's Republic of China on the Protection of Consumer Rights and Interests when consumers whose lawful rights and interests are infringed upon in purchasing or using commodities. We may seek remedies from the manufacturer if the product are not meeting the conditions or not free from serious defects.	On the basis that CUP-SFJH is a cosmetic product which is not regulated as drug or pharmaceutical product, 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-SFJH.

Products	Mode of Distribution	Distribution channels	Sales liability(ies) under the relevant mode of distribution	Analysis regarding the two- invoice system in the PRC
Routine Skin Care Products	Direct sales	Tmall and a number of other e-commerce platforms, including Douyin and Xiaohongshu	As advised by our PRC Legal Advisor, we might be held liable under the E-commerce law as an e-commerce operator and may be liable under the Law of the People's Republic of China on the Protection of Consumer Rights and Interests when consumers whose lawful rights and interests are infringed upon in purchasing or using commodities. We may seek remedies from the manufacturer if we received complaints from our customers.	On the basis that Routine Skin Care Products are not regulated as drugs or pharmaceutical products, our PRC Legal Advisor is of the view that the PRC laws and regulations governing pharmaceutical operations (including two-invoice system) are not applicable to our sales of Routine Skin Care Products.
	Sales to distributors	Three third party distributors in the PRC which sell the products to customers offline through their stores or online through the e-commerce platforms	As advised by our PRC Legal Advisor, we may be liable under the Law of the People's Republic of China on the Protection of Consumer Rights and Interests when consumers whose lawful rights and interests are infringed upon in purchasing or using commodities. We may seek remedies from the manufacturer if we received complaints including the safety issues from our customers.	On the basis that Routine Skin Care Products are not regulated as drugs or pharmaceutical products, our PRC Legal Advisor is of the view that the PRC laws and regulations governing pharmaceutical operations (including two-invoice system) are not applicable to our sales of Routine Skin Care Products.

### **INTELLECTUAL PROPERTY**

Intellectual property ("**IP**") rights are central to the success of our business. Our commercial future will depend, in part, on our ability to acquire and protect our intellectual property rights for commercially significant technologies, inventions and know-how. This could involve the acquisition of new patents, the defense of existing patents, and the protection of our trade secrets. We will also have to operate without infringing, misappropriating, or otherwise violating third parties' valid, enforceable 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. We plan to continue to file additional patent applications for CU-20401 and its indications in order to obtain exclusivity protection after the expiration date of the patent for CU-20401 in 2038. The following table sets forth an overview of our material granted patents and patent applications in connection with our product candidates as of the Latest Practicable Date:

Related Product	Name of Patent	Jurisdiction	Status	Patent Expiration <sup>(1)</sup>	Market Commercial Rights of the Company
CU-20401	A recombinant variant collagenase preparation method and use thereof	Mainland China	Granted <sup>(2)</sup>	2038-07-30	Exclusive
CU-40102	Spray dispenser	Mainland China	Granted	2037-06-30	Exclusive <sup>(3)</sup>
CU-40102	Film-forming liquid formulations for drug release to hair and scalp	Hong Kong Hong Kong	Granted Granted	2037-06-30 2029-07-29	Exclusive <sup>(3)</sup> Exclusive <sup>(3)</sup>
CU-40101	Small molecule compound and synthesizing method and uses thereof	Mainland China Japan	Granted Granted	2034-08-14 2035-08-13	Exclusive <sup>(4)</sup> Exclusive <sup>(4)</sup>
CU-10101	A type of diphenylethylene derivative and use thereof	Mainland China	Granted	2033-10-14	Exclusive
CU-10101	Hydroxydiphenylethylene Class Compound Ointment and the Use and Preparation Method Thereof	PCT	Pending	N/A	Exclusive
CU-10101	Hydroxystilbene Class Compound Ointment and the Use and Preparation Method Thereof	РСТ	Pending	N/A	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 doest 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.
- (3) We have the exclusive right to use these three patents in the field relating to androgenic alopecia.
- (4) We have the exclusive right to use these two patents in the field of dermatology indications including scalp disease treatment.

The term of an individual patent may vary based on the countries/regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned, or in-licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and the methods of manufacturing the same.

We rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality arrangements with contractors. We have entered into confidentiality and non-compete agreements with our key employees and employees involved in R&D, pursuant to which intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property. We also have established an internal policy governing the confidentiality of all company information. Despite the measures we have taken to protect our intellectual property, our proprietary information may be obtained by unauthorized parties. For more details, see "Risk Factors – Risks Relating to Our Intellectual Property Rights" in this Document.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises as well as physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. For more details, see "Risk Factors – Risks Relating to Our Operations – Our internal information technology and other infrastructure, or those used by our CROs, CDMOs or other contractors or consultants, may fail or suffer security breaches" in this Document.

As of the Latest Practicable Date, we owned 102 registered trademarks and filed 63 trademark applications in Mainland China and Hong Kong. We can also seek trademark protection for our Company and our corporate logo in additional jurisdictions that are available and appropriate. We are also the registered owner of one domain name.

Nevertheless, we may not be able to identify all of the patent applications filed by other market players. Additionally, patent infringement claims often involve an analysis of complex legal and factual issues, the determination of which are often difficult to foresee. If any of our competitors alleges patent infringement claims against us before a court, there is no assurance that the judgment of the court regarding the patent infringement claims will be in our favor. Furthermore, new patents obtained by our competitors could threaten a product's continued life in the market even after it has already been introduced.

As of the Latest Practicable Date, we hold one patent in relation to our Core Product. After patent acquisition of CU-20401, Rejuven does not hold any other patents in relation to CU-20401 within Asia. Our Directors believe that such a patent has covered all the key characteristics of the Core Product for the PRC market and the Company's exposure to any objection or claim from other market players concerning similar technologies or features underlying their granted patents or patent applications is remote. To our best knowledge, we do not expect any legal impediment in obtaining approval for each pending patent application. During the Track Record Period and up to the Latest Practicable Date, we had not received or aware of any actual, pending or threatened patent infringement claims against us. 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. Based on the freedom-to-operate analysis conducted on the key characteristics of our Core Product in the PRC, we did not identify any issued patents in the PRC owned by third parties which may affect our R&D, manufacturing and commercialization rights of our Core Product in Mainland China.

We have established a set of intellectual property management measures in order to strengthen the protection of intellectual property, encourage the enthusiasm of invention, and promote the application of scientific research results. The employee contracts also typically include undertakings regarding assignment of inventions and discoveries made during the course of his or her employment. During the term of the contract, all technical achievements made by the employee using the production, management and technical information of the Company shall be the result of his employment. Apart from the right of attribution, all other intellectual property rights in relation to these achievements shall belong to the Company. During the term of the contract and for one year after termination of such contract, all technical achievements made by the employee while carrying out tasks or engaging in production or business activities for the Company, and using the production, management and technical information of the company, shall belong to the Company in all respects (including ownership, use rights, transfer rights and all other intellectual property rights). If such technical achievements are subsequently patented, the patent rights and application rights also belong to the Company.

### **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 amounted to RMB381,000 and RMB4,646,000 in 2021 and 2022, respectively. In 2021 and 2022, our five largest customers together accounted for 18.7% and 40.9%, respectively, of our total revenues during those periods, and our largest customer accounted for 18.7% and 39.4%, respectively, of our total revenues during those periods. We generally grant a credit term of less than 30 days or 15 days from the first day of the following month after receipt of value-added tax invoice to our customers. None of our five largest customers in each year is our supplier. For more details, see "Risk Factors – Risks Relating to Our Reliance on Third Parties – We are subject to credit risks of our customers. If we experience delays in collecting or if we are unable to collect payments from customers, our cash flows and operations could be adversely affected".

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.

The tables below set forth certain information about our five largest customers in each year in terms of revenue (in descending order) generated during the Track Record Period:

Customer	Years of relationship as of December 31, 2021	Background and business activities	Product sold	Credit term	For the ye December Sales amount (RMB'000 percen	31, 2021 Percentage of revenue 0, except
Customer A	One	Customer A is a reputable and leading provider of a suite of health and well-being products headquartered in Hong Kong	CUP-MNDE	30 days after for the second and subsequent purchases	381	18.7%

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## BUSINESS

	Years of relationship as of				For the ye December	31, 2022
Customer	December 31, 2022	Background and business activities	Product sold	Credit term	Sales amount (RMB'000 percent	
Customer A	Two	Customer A is a reputable and leading provider of a suite of health and well-being products headquartered in Hong Kong	CUP-MNDE	30 days after for the second and subsequent purchases	4,473	39.4%
Customer B	Two	Customer B is an integrated regional pharmaceutical distribution company headquartered in Hainan	CU-40102; CU-10201	10 working days each month upon receipt of payment from end-users	105	0.9%
Customer C	Less than one	Customer C is a provider of supply chain services, headquartered in Guangdong	Routine Skin Care Products	15 days from the first day of the following month after receipt of value-added tax invoice	64	0.6%
Customer D	Less than one	Customer D is a provider of medical, health and well-being products headquartered in Shanghai	Routine Skin Care Products	N/A	2	-
Customer E	Less than one	Customer E is a provider of wholesale headquartered in Shanghai	Routine Skin Care Products	N/A	2	-

The increasing concentration of customers during the Track Record Period was due to the fact that we engaged a distributor in Hong Kong for the commercialization of CUP-MNDE and a distributor in Hainan for the pilot commercialization of CU-40102 and CU-10201, which accounted for the majority of our total revenue during the Track Record Period.

We endeavor to expand and diversify our customer base by expanding direct sales channels as well as our distributor base to substantively reduce our top customer concentration going forward. We have been enhancing our direct marketing efforts, in particular our online marketing efforts, so as to increase the proportion of our direct sales, and plan to increase our sales to other distributors by launching new product categories to our existing distribution

network for them to sell more of our pipeline products. In addition, we will also further expand our distributor base across China, in particular the northwest and south central regions of China and the medical institutions coverage. With the tailwind of a rapid growing market and our commitment to diversifying our customer base, we believe that we are well-positioned to reduce the customer concentration in the future. See "Risk Factors – Risks Relating to Our Business and Industry – We depend on our distributors for a large portion of our total revenue, over whom we have limited control, during the Track Record Period, which exposes us to significant concentration risk."

### **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 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.

In addition, we believe that adequate alternative sources for such suppliers exist, and we have developed alternative sourcing database for these suppliers. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. We generally have credit periods of up to 30 days.

Below is a summary of the key terms of a typical agreement with our CROs and CDMOs.

- *Services*. The CRO or CDMO provides us with services such as implementing a clinical research project, manufacturing products for trial purpose as specified in the master agreement or work order.
- *Term.* The CRO or CDMO is required to perform its services according to the prescribed timeframe set out in the master agreement or a work order.
- *Payment*. We are required to make payments to the CRO or CDMO according to the payment schedule agreed by the parties.
- *Confidentiality.* We and the CRO or CDMO agree to keep confidential any information in relation to the performance of the master agreement.
- *Intellectual Property.* We own all intellectual property derived from the clinical research project, and we are entitled to apply patent for such intellectual properties.

The tables below set forth certain information about our five largest suppliers in each year in terms of total purchases during the Track Record Period:

	Years of relationship as of December 31,	Product or		For the ye December Purchase	
Supplier	2021	service supplied	Credit Term	amount (RMB'000	<b>purchases</b> ). except
				percent	
Supplier A	Three	Human resources and employees remuneration services	Upon the invoice issued <sup>(1)</sup>	34,978	28.2%
Parexel China Co. Ltd.	One	R&D services	30 days <sup>(2)</sup>	14,702	11.8%
Supplier C	Three	R&D services; licensing	20 working days <sup>(3)</sup>	10,000	8.1%
Bestudy (Shanghai) Medical Technology Co., Ltd.	Two	R&D services	six months for the first payment and one month for remaining payments <sup>(4)</sup>	7,784	6.3%
Hangzhou Tigermed Consulting Co., Ltd.	One	R&D services	30 days <sup>(5)</sup>	6,232	5.0%

Notes:

- 1. the amount will be settled by bank transfer upon the invoice issued
- 2. the amount will be settled by bank transfer within 30 days upon the invoice issued
- 3. the amount will be settled by bank transfer within 20 working days upon the invoice issued
- 4. the amount will be settled by bank transfer within six months for first payment and within one month for remaining payments upon the invoice issued
- 5. the amount will be settled by bank transfer within 30 days upon the invoice issued

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### BUSINESS

	Years of relationship as			For the ye December	
Supplier	of December 31, 2022	Product or service supplied	Credit Term	Purchase amount (RMB'000 percent	of total purchases
Supplier A	Four	Human resources and employees remuneration services	Upon the invoice issued <sup>(1)</sup>	53,808	15.9%
Supplier E	Two	Decoration and electrical and mechanical engineering services	30 working days <sup>(2)</sup>	42,626	12.6%
Supplier F	Less than one	Indoor design and decoration services	30 working days <sup>(3)</sup>	20,884	6.2%
Hangzhou Tigermed Consulting Co., Ltd.	Two	R&D services	30 days <sup>(4)</sup>	15,086	4.5%
Parexel China Co. Ltd.	Two	R&D services	30 days <sup>(5)</sup>	14,864	4.4%

Notes:

- 1. the amount will be settled by bank transfer upon the invoice issued
- 2. the amount will be settled by bank transfer within 30 working days upon the invoice issued
- 3. the amount will be settled by bank transfer within 30 working days upon the invoice issued
- 4. the amount will be settled by bank transfer within 30 days upon the invoice issued
- 5. the amount will be settled by bank transfer within 30 days upon the invoice issued

We engaged a third-party human resource agency which is also one of our suppliers, to pay the salary and remuneration to our employees. The third-party human resource agency charges a fixed fee for each relevant employee. The reason for engaging such services was that a professional external human resource team can help us to effectively address all payroll matters so that we can focus more on our R&D activities. The high expenses for 2021 and 2022 were due to the need to recruit more employees for our activities and to engage external human resources to assist with the our day-to-day administrative operations.

Our Directors have assessed the service fee for distribution of our employee's salary and work scope of the external agency by comparing the fee rates available in the market, as well as assessing its costs and the estimated transaction amounts in the future. As such, our Directors believe that the service fee is fair and reasonable.

#### COMPETITIONS

When we were established in 2019, we were strategically positioned as 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 aim to provide a one-stop solution for dermatology patients to achieve cross-selling in the future.

To achieve this goal, we strategically focused our initial development efforts on the most technologically challenging therapeutic areas with high clinical and commercial value such as skin diseases treatment and care, and then quickly expanded into other critical dermatology therapeutic areas. Since 2019, we have started acquiring or licensing other dermatology products to round out our pipeline, in addition to our internally developed portfolio. We are also partnering with multinational companies to distribute CUP-SFJH and CUP-MNDE to build our brand goodwill in the skin diseases and care and scalp diseases and care therapeutic areas, which will eventually translate into patient loyalty and cross-selling once other products launch market.

China's broader dermatology treatment and care market is competitive, characterized by rapid changes from technological advances and scientific discoveries. We have faced, and may continue to face, competition mainly from international and domestic pharmaceutical and biotechnology companies, academic institutions and public and private research institutions in the areas in which we primarily operate our current business and seek future expansion. See "Industry Overview" for more details of the competitive landscape of each relevant market regarding our pipeline products.

We believe our principal competitive advantages include integrated capabilities, extensive technology platforms, comprehensive pipeline and seasoned management team. However, some of our current or future competitors may have longer operating history, higher market recognition and degree of acceptance, and stronger R&D, manufacturing and commercialization capabilities than us.

### GOVERNMENT GRANTS, AWARDS AND RECOGNITIONS

The following table sets forth some of the important accreditations and awards we had received from the relevant authorities and organizations in China as of the Latest Practicable Date in recognition of our R&D capabilities:

Year	Accreditation/Award	Accreditation Organization
2021	The "Flying Phoenix Talent Plan" Entrepreneurial Leader Project ("飛鳳人才計劃"創業領軍人才專案)	Wuxi High-tech Zone (Xinwu District) Talent Work Leading Group Office (無錫高新區(新吳區)人才工作領導小 組辦公室)
		Science and Technology Bureau of
		Wuxi High-tech Zone (Xinwu District) (無錫高新區(新吳區)科技局)
2021	Zhangjiang Science City Special Funds Policy (張江科學城專項資金政策)	Shanghai Zhangjiang Science City Construction Management Office (上海市張江科學城建設管理辦公室)
2022	The First Batch of Science and Technology-Based Small and Medium Enterprises of Jiangsu Province in 2022 (江蘇省2022年第1批入庫科技型 中小企業)	Science and Technology Department of Jiangsu Province (江蘇省科技廳)
2022	The First Batch of Science and Technology-Based Small and Medium Enterprises of Shanghai in 2022 (上 海市2022年第1批入庫科技型中小企 業)	Shanghai Science and Technology Commission (上海市科學技術委員會)

### **INSURANCE**

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover employee benefits liability and adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. For more details, see "Risk Factors – Risks Relating to our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources" in this Document.

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

### **EMPLOYEES**

As of the Latest Practicable Date, we had 157 employees in total. Among the 157 employees, 97 are stationed in our headquarters in Shanghai. As of December 31, 2022, we had a total of 175 employees, of which 172 employees or 98.3%, are based in China, and 3 employees or 1.7%, are based in Hong Kong. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Eurotion	Number	Percentage	
Function	Number	of total	
R&D	32	20.4%	
Manufacturing and Quality Control	32	20.4%	
Medical and Regulatory Affairs	31	19.7%	
Sales, Marketing and Administration	62	39.5%	
Total	157	100%	

We enter into individual employment contracts with our employees covering salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. The contracts also typically include confidentiality and non-competition clauses.

To maintain our workforce's quality, knowledge, and skill levels, we provide continuing education and training programs, to improve their technical, professional or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including bonuses and share-based compensation, particularly our key employees.

Our employees' remuneration comprises salaries, bonuses, provident funds, social security contributions, and other welfare payments. We have made contributions to our employees' social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations. Our PRC Legal Advisors have confirmed that we have complied with all material statutory social security insurance fund and housing fund obligations applicable to us under the PRC laws and regulations during the Track Record Period and as of the Latest Practicable Date.

### LAND AND PROPERTIES

As of the Latest Practicable Date, we do not hold any real property. As of the Latest Practicable Date, we leased eight properties with an aggregate GFA of approximately 21,100.7 sq.m. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration.

The following table sets forth the details of our leased properties as of the Latest Practicable Date:

Usage	Location	GFA (sq.m)	Lease Term
Office	Jingan District, Shanghai	1,546.2	September 22, 2020 to January 7, 2026
R&D Site	Minhang District, Shanghai	6,253.4	July 21, 2022 to July 20, 2028
Manufacturing Plant, Office	Pudong New District, Shanghai	1,171.9	August 7, 2020 to August 7, 2023
Production Site	Wuxi, Jiangsu	11,123.0	October 1, 2021 to September 30, 2033
Office	Wuxi, Jiangsu	339.6	October 1, 2021 to September 30, 2023
Office	Dongcheng District, Beijing	176.8	November 1, 2021 to October 31, 2024
Office	Haidian District, Beijing	481.1	March 15, 2022 to September 15, 2023
Office (licensed property)	Kowloon, Hong Kong	8.7	1

#### ENVIRONMENTAL, SOCIAL, AND GOVERNANCE

### Governance

We acknowledge our environmental protection and social responsibilities and are aware of the climate-related issues that may impact our Group's business operation. We are committed to complying with environmental, social and governance ("ESG") reporting requirements upon [REDACTED].

We have established a set of ESG policies ("ESG Policy") covered under relevant international standards. We endeavor to reduce negative impacts on the environment through our commitment to energy saving and sustainable development. We plan to adopt governance measures in place to comply with all ESG-related laws and regulations and to monitor and collect ESG-related data for preparing disclosure in compliance with the requirements of the Environmental, Social and Governance Reporting Guide in Appendix 27 to the Listing Rules,

upon the [**REDACTED**] and when appropriate. We are preparing and will establish an ESG policy in accordance with the standards of Appendix 27 to the Listing Rules, which outlines, among others (i) reduction of greenhouse gas emissions, (ii) treatment of exhaust gas and solid waste, (iii) adoption of materials that cause minimum environmental concerns to the extent possible, and (iv) conservation of energy, among other aspects. We continue to promote work-life balance and create a positive workplace for all of our employees. For social matters, we have adopted policies related to (i) product quality, (ii) employee health, compensation and benefits, (iii) employee training, wellness and professional and personal development, and (iv) employee complaint handling, among other aspects. Our ESG Policy also sets out different parties' respective responsibilities and authority in managing the ESG matters. Our Board has overall responsibility for overseeing and determining our Group's environmental, social, and climate-related risks and opportunities impacting our Group, establishing and adopting the ESG Policy and targets of our Group, and reviewing our Group's performance annually against the ESG targets and revising the ESG strategies as appropriate if significant variance from the target is identified. As confirmed by Frost & Sullivan, the Group's resource consumption and pollutant management are in line with the industry average.

Our Board has established an ESG working group that comprises our executive Directors and management representatives. The ESG working group will have a specific focus on environmental matters, such as energy consumption, pollutants, greenhouse gas emissions and reporting, as well as waste management and recycling efforts. The ESG working group serves as a supportive role to our Board in implementing the agreed ESG Policy, targets and strategies; identifying and assessing ESG-related matters, including climate-related risks, by taking into consideration the metrics and targets stipulated in Appendix 27 to the Listing Rules and applicable laws, regulations and industry standards; managing how our Group adapts its business in light of climate change; collecting ESG data from different parties while preparing for the ESG report; and continuous monitoring of the implementation of measures to address our Group's ESG-related risks. The ESG working group has to report to our Board on a semi-annual basis on the ESG performance of our Group and the effectiveness of the ESG systems.

### **Potential Impacts of ESG-Related Risks**

We are subject to various ESG related laws and regulations in China, and our operations are regularly inspected by local government authorities. During the Track Record Period and up to the Latest Practicable Date, we have not received any fines or penalties associated with the breach of any environmental laws or regulations. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. We will engage an ESG advisor and will conduct an enterprise risk assessment to cover the current and potential ESG risks faced by the Group in due course, and aims to complete the entire assessment by the fourth quarter of 2023. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

In view of the nature of our business, to the best knowledge of our directors, the climate change will not have any major impact on our business operation. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of environmental, social and climate-related issues.

Potential transition risk may result from a lower-carbon economy, which entails climate-related regulations and policy change and reputational risk. Currently, the National Development and Reform Commission and the Ministry of Ecology and Environment have jointly issued the Opinions on Further Strengthening the Cleanup of Plastic Pollution, laying out a five-year roadmap to restrict the use, production and sale of plastic products by 2020, 2022, and 2025, respectively. Our Group will work with the suppliers to comply with such regulations, and we will monitor the scope to ensure our works meet the expectations of the regulators.

Set forth below summarizes the climate-related risks our Group identified over the short, medium and long term.

		Risks		<b>Potential Impacts</b>	
Short term (current annual reporting period)	•	Sustained elevated temperature	•	Reduced revenue from damage to assets, disruption to third-party logistic providers or third-party manufacturers	
Medium term (one to three years)			•	Increased operating expenses	
Long term (four to ten years)	•	Change in climate- related regulations	•	Increased cost of inventories sold due to policy changes	
	•	Shifts in customer preferences	•	Reduced demand for goods and services	

## Strategies in addressing ESG-related risks

We will adopt various strategies and measures to identify, assess, manage and mitigate environmental, social and climate-related risks, including but not limited to:

- reviewing and assessing the ESG reports of similar companies in the industry to ensure that all relevant ESG-related risks are identified on a timely basis.
- discussing among management from time to time to ensure all the material ESG areas are recognized and reported.
- discussing with key stakeholders on key ESG principles and practices to ensure that the significant aspects are covered.
- organizing a specific ESG risk management process to identify and consider ESG risks and opportunities separate from other business risks and opportunities.
- setting targets for environment KPI, including with regard to emission, pollution and other impact on the environment aimed at reducing emissions and natural resource consumption.

We will adopt comprehensive measures to mitigate environmental impact from our business, strategy and financial performance in the near, medium and long term, as summarized below:

Focus area	Key measures		
Exhaust gas management	• Adopt exhaust gas treatment system and install active carbon filters		
Greenhouse gas management	• Increase the use of clean energy		
	• Use energy efficient equipment		
Sewage management	• Install sewage treatment system		
Solid waste management	• Require proper handling and disposal of solid waste		
	• Set up hazardous waste storage sites in accordance with relevant standards and establish standardized hazardous waste management system		
	• Engage qualified third-party suppliers for solid		

Engage qualified third-party suppliers for solid waste disposal

Focus area	Key measures
Energy and resource conservation	• Improve energy-saving features such as energy- saving transformers
	• Conserve water by recycling rain water and installing low-flow valves

Our Group will conduct an enterprise risk assessment at least once a year to cover the current and potential risks faced by our Group, including, but not limited to, the risks arising from the ESG aspects and strategic risk around disruptive forces such as climate change. Our Board will assess or engage an external expert to evaluate the risks and review our Group's existing strategy, target and internal controls, and necessary improvement will be implemented to mitigate the risks. Our Board, Audit Committee, and the ESG working group will maintain oversight of our Group's approach to risk management, including climate-related risks and risks monitored as part of the standard operating processes to ensure the appropriate mitigations are in place of the regular management reviews.

The decision to mitigate, transfer, accept or control risk is influenced by various factors such as government regulation and public perception. Our Group will incorporate climaterelated issues, including physical and transition risk analysis, into our risk assessment processes and risk appetite setting. If the risk and opportunities are considered material, our Group will make reference to them in the course of the strategy and financial planning process. Upon annual review of the environmental, social and climate-related risks and our Group's performance in addressing the risks, we may revise and adjust the ESG strategies as appropriate.

### Metrics and Targets

We monitor the following metrics to assess and manage the environmental and climate-related risks arising from our business and manufacturing operations:

### Resource consumption

- *Electricity consumption.* We have monitored our electricity consumption levels and implement measures to improve energy efficiency since 2021. For the years ended December 31, 2021 and 2022, our electricity consumption levels were 765,628.7 kWh and 1,592,892.6 kWh, respectively.
- *Water consumption.* We have monitored our water consumption levels and implement measures to promote water conservation since 2021. For the years ended December 31, 2021 and 2022, our water consumption levels were 908.3 m<sup>3</sup> and 13,259.1 m<sup>3</sup>, respectively.

#### Pollutant management

- Greenhouse gas discharge. We have monitored our greenhouse gas ("GHG") discharge levels on a periodic basis since 2021. For the years ended December 31, 2021 and 2022, our GHG emissions were approximately 445.3 ton of  $CO_2$  equivalent and 921.3 ton of  $CO_2$  equivalent, respectively. Such exhaust gas was properly treated prior to discharge.
- *Hazardous waste discharge*. We have monitored our hazardous waste discharge levels on a periodic basis since 2021. For the years ended December 31, 2021 and 2022, our hazardous waste discharge levels were approximately 11.5 tons and 7.6 tons, respectively.

Our Board will set targets for each material KPIs at the beginning of each financial year in accordance with the disclosure requirements of Appendix 27 to the Listing Rules and other relevant rules and regulations upon [**REDACTED**]. The relevant targets on material KPI will be reviewed on an annual basis to ensure that they remain appropriate to the needs of our Group. In setting targets for the ESG-related KPIs, we have taken into account our respective historical consumption or discharge levels during the Track Record Period, and have considered our future business expansion in a thorough and prudent manner with a view of balancing business growth and environmental protection to achieve sustainable development. We will make continuous efforts in working towards the target of reducing our electricity and water consumption, gas emissions and hazardous wastes discharge per thousand dollars of R&D expense by 5% in 2023.

Our total cost of compliance with environmental protection and health and safety laws and regulations for 2021 and 2022 was approximately RMB104,080 and RMB72,117.3, respectively. We do not expect our costs of complying with current and future environmental protection and health and safety laws to increase significantly going forwards.

### **Green Packaging**

We are constantly searching for ways to minimize the environmental impact of our products. We have sought to implement green packaging initiatives for our products. Eco-friendly packaging solutions use materials and manufacturing techniques which in turn allow us to reduce the carbon footprint of our business activities.

### Animal Clinical Trial

During the Track Record Period, we had not conducted any animal clinical trials or studies with ethical issues, or with raw materials that are not environmental friendly. We aim to prevent unnecessary animal experiments and reduce the use of raw materials that are not environmental friendly for our clinical trials, and follow applicable regulations, industry best practices and ethical standards for our daily operations.

#### Workplace Safety

We have adopted and maintained a series of rules, standard operating procedures, and measures to maintain our employees' healthy and safe environment. We implement safety guidelines to set out information about potential safety hazards and procedures for operating in the manufacturing facilities. We require new employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. Also, we have policies in place and have adopted relevant measures to ensure the hygiene of our work environment and the health of our employees.

#### **Product Safety**

Our online brand promotional and advertising campaigns are featured with activities providing customers with professional skincare knowledge and the actual efficacies of our products. For example, we inform our customers that certificates have been obtained from professional testing institutions that conducted efficacy tests and safety assessments on our products. Through these results, we communicate to our customers about the reliability and efficacies of our products.

#### **Supply Chain Management**

Our suppliers mainly include raw material suppliers and packaging materials suppliers, which could all profoundly impact the safety and quality of our products as well as our overall brand image. Therefore, we have a supplier management policy, based on which we evaluate our suppliers carefully according to their historical quality performance.

In addition, we also encourage our suppliers to comply with relevant environmental and social regulations. Since we are not engaged in manufacturing of products and we do not directly perform the delivery of goods, we do not purchase any cartons or other packaging materials to package the products we sold under the distribution method. For the products we procured from our partners, their packaging involves usage of packaging materials such as packaging tapes, labels and cartons. We commit to reducing our environmental footprint. We adhere to the principles of simplicity, high efficiency and convenient use for customers, and expect to collaborate with our suppliers to package the products in a more environment friendly manner. We have also included anti-corruption clauses in our agreements with our suppliers to prevent collusion and corruption.

### **Data Privacy Protection**

We have established procedures to protect the confidentiality of patients' data. We implement strict internal policies such as Information Management Policies and Data Privacy Protection Policies to govern the collection, handling, storage, retrieval of, and access to our patients' personal data and medical records and protect the security and confidentiality of personal information to ensure compliance with all applicable national or international rules and regulations on data protection and privacy. We usually require our personnel to collect and

safeguard personal information in their possession. Our information technology network is configured with multiple layers of protection to secure our databases and servers. We have also implemented a variety of protocols and procedures, such as regular system checks, password policy, server access logging, network access authentication, user authorization review and approval and data back-up, as well as data recovery test, to safeguard our data assets and prevent unauthorized access to our network. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel. In order to strengthen the management of our database, ensure the normal and effective operation of the database, and ensure the security of the database, we have designated database administrators to carry out the responsibilities of daily maintenance, authority control, security protection and other management of the database. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the informed consent form.

Furthermore, we enter into confidentiality agreements with our employees who have access to any aforementioned privacy information. The confidentiality agreements provide that, among others, these employees are legally obligated not to misuse the confidential information while in office, to surrender all confidential information in possession while resigning, and to retain their confidential obligations after they leave office. We also implement a series of measures to ensure our employees' compliance with our data security measures. For instance, we require new hires to receive on boarding training on data security and employees to be familiarised with the relevant data security policies. Employees shall acknowledge to us that they understand and will follow our internal policies.

During the Track Record Period, we did not experience any breach of confidential client information or any other client information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations.

Our PRC Legal Advisors have confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material claim or penalty in relation to health, work safety, product safety, data privacy and social and environmental protection, had not been involved in any accident or fatality and had been in compliance with the relevant PRC laws and regulations in all material aspects.

#### PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, our PRC Legal Advisors confirmed we had obtained all requisite licenses, approvals and permits from relevant PRC authorities that are material to our operations in the PRC, and such licenses, permits and certifications all remain in full effect. For more details regarding the laws and regulations to which we are subject, see "Regulatory Overview" in this Document. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. To the best knowledge of our PRC Legal

Advisors, there is no material legal impediment in renewing such licenses, permits, approvals and certificates as they expire in the future as long as we are in compliance with applicable laws, regulations and rules. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

Licenses/Permit	Issuing Authority	Grant Date	Expiry Date
Notice of Approval for Clinical Drug Trials (No. 2021LP00444) ((藥物臨床試驗批准通知書) (編號: 2021LP00444))	NMPA	April 6, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP01553) ((藥物臨床試驗批准通知書) (編號: 2021LP01553))	NMPA	September 27, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP02036) ((藥物臨床試驗批准通知書) (編號: 2021LP02036))	NMPA	December 17, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP02037) ((藥物臨床試驗批准通知書) (編號: 2021LP02037))	NMPA	December 17, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP02038) ((藥物臨床試驗批准通知書) (編號: 2021LP02038))	NMPA	December 17, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP02039) ((藥物臨床試驗批准通知書) (編號: 2021LP02039))	NMPA	December 17, 2021	N/A

Licenses/Permit	Issuing Authority	Grant Date	Expiry Date
Notice of Approval for Clinical Drug Trials (No. 2021LP01219) ((藥物臨床試驗批准通知書) (編號: 2021LP01219))	NMPA	August 4, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2022LP00366) ((藥物臨床試驗批准通知書) (編號: 2022LP00366))	NMPA	March 7, 2022	N/A
Notice of Approval for Clinical Drug Trials (No. 2022LP01808) ((藥物臨床試驗批准通知書) (編號: 2022LP01808))	NMPA	November 1, 2022	N/A
Pharmacy and Poisons Ordinance Wholesale Dealer Licence (No. 72/2A/2022) ((藥劑業及毒藥條例批發商牌照) (編號: 72/2A/2022))	Pharmacy and Poisons Board	October 3, 2022	October 2, 2023

### LEGAL PROCEEDINGS AND COMPLIANCE

#### **Legal Proceedings**

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings. We are committed to maintaining the standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

### Legal Compliance

Our PRC Legal Advisors confirmed that during the Track Record Period and up to the Latest Practicable Date, we had complied with all material applicable PRC laws and regulations. Our Directors confirmed that we were not involved in any material or systemic non-compliance incidents.

Our compliance team is responsible for building, developing and improving our compliance management system to ensure our compliance culture is embedded into everyday workflow. The team conducts compliance training for target groups and identifies, assesses, and reports compliance risks and expectations in a timely manner. Our compliance team will also work with the senior management team to monitor and evaluate the effectiveness of our compliance function and structure to ensure that we comply with the applicable laws and regulations.

#### **Non-Compliances**

During the Track Record Period and up to the Latest Practicable Date, we experienced certain non-compliance incidents, the details of which are set forth below:

#### **Property Issues**

We leased one property for office use from an Independent Third Party. As advised by our PRC Legal Advisors, such parcel of land was obtained by the landlord by way of government allocation (劃撥地). In order to lease allocated land, one must obtain necessary approval from relevant government authorities and comply with legal procedures to convert allocated land into assigned land (出譲地). Therefore, the lease entered into by us may be deemed invalid and unenforceable under the applicable PRC laws. The premises is used for general office space and a comparable replacement site is readily available in the vicinity. As of the Latest Practicable Date, we were not aware of any challenge by a third party or government authority on the titles of any of our leased properties that might affect our current occupation.

In addition, pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, the lease agreements shall be filed for registration and property leasing filing certificates shall be obtained. During the Track Record Period and as of the Latest Practicable Date, eight of our lease agreements for properties in China have not been registered with relevant authorities in China. The registration of these relevant lease agreements requires additional steps to be taken by the lessors which are beyond our control. We cannot assure you that the lessors will be cooperative and that we can complete the registration of these lease agreements. We also maintain a pool of site candidates, and believe we would be able to relocate to a different site relatively easily should we be required to do so. As advised by our PRC Legal Advisor, if we cannot complete the registration of lease agreement, we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each of the lease agreements, resulting in an aggregate maximum exposure to penalties of RMB80,000. Such noncompliance does not affect the validity of the property lease agreement, and we believe such non-compliance is unlikely to have a material adverse effect on our business operations and financial performance.

We had one leased property in Shanghai with a leased period of three years. The lease agreement will be terminated in August 2023 with an option of renewal of three years. For our early termination, the landlord is entitled to charge a three-month rental fee as a penalty. This property is used as a manufacturing plant and office, for which we did not complete the required fire safety filing. As advised by our PRC Legal Advisor, the maximum penalty that we could incur in connection with such non-compliance incidents shall be a fine of RMB5,000 for failure to complete the fire safety filing. Our PRC Legal Advisor is of the view that the risk that we would be subject to any material retrospective administrative penalties by the relevant governmental authorities due to the non-compliance relating to fire safety with respect to the leased property is remote on the following bases: (i) we had not been subject to any material

administrative penalties with respect to the relevant fire safety non-compliance incidents during the Track Record Period, (ii) we will fully comply with such order in the event we are ordered by the relevant governmental authorities to rectify the relevant fire safety noncompliance incidents, and (iii) we have ceased to use the leased property and it has been agreed that the lease agreement will be terminated. We have relocated to another leased property and moved the devices and facilities to the property, which has received the Notice of Completion and Acceptance for Construction Project that the Company had completed the fire safety filing for the new property.

We aim to enhance our internal control measures and procedures with respect to the foregoing to manage associated risks and prevent re-occurrence of such non-compliance incidents. We provide regular trainings on fire safety to our staff, which cover key aspects of our daily operations. We also organize fire drills on a regular basis to increase fire safety awareness of our employees.

#### Social insurance and the housing provident fund issues

During the Track Record Period, we engaged third-party human resource agency to pay social insurance premium and housing provident funds for 10 of our employees. Pursuant to the agreement entered into between such third-party human resources agency and us, the third-party human resources agency have the obligation to pay social insurance premium and housing provident funds for our relevant employees on behalf of us. We expect to make contributions to the social insurance plans and the housing provident fund to those 10 employees after the expiration of the term of the agreement between third-party human resources agency and us. As of the Latest Practicable Date, we had not received any administrative penalty or labor arbitration application from employees for its agency arrangement with third-party human resources agency. These ten employees have never pursued any claims against us with the competent authorities. As advised by our PRC Legal Advisor, considering the facts stated above, the risk of us being subject to material penalties as a result of paying the social insurance premium or housing provident funds through third-party agency and thus have any material adverse effect on our financial condition or results of operations taken as a whole is relatively low. However, if the local governments determine the use of third-party agency to pay social insurance and housing provident funds to be non-compliant in the future or such human resource agency fail to pay the social insurance premium or housing provident funds for and on behalf of our employees as required by applicable PRC laws and regulations, we may be subject to additional contribution, late payment fee and/or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance and housing provident funds as an employer or be ordered to rectify. The maximum exposure of penalties for the above non-compliance is that if we fail to pay social insurance contributions on time and in full, the social insurance agency shall place an order with us demanding full payment within a prescribed period, and an overdue payment fine at the rate of 0.5% shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine above the overdue amount but less than its triple shall be demanded by the authoritative administrative department.

To ensure compliance with the relevant regulations relating to social insurance and housing provident fund in the future, we have enhanced our internal control measures requiring social insurance and housing provident fund contributions to be made in compliance with relevant PRC laws and regulations in all material aspects. In particular, we plan to regularly review and monitor the reporting and contributions of social insurance and housing provident fund and consult our PRC legal counsel on a regular basis to keep us abreast of relevant regulatory developments.

## RISK MANAGEMENT AND INTERNAL CONTROL

### **Risk Management**

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. For more details, see "Risk Factors – Risks Relating to Our Operations." Our Directors oversee and manage the overall risks associated with our operations. We have prepared written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [**REDACTED**], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an Audit Committee to review and supervise our financial reporting process and internal control system.
- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure;
- provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations; and
- attend training sessions by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies listed in Hong Kong.

## **Internal Control**

We have employed an independent internal control consultant to assess our internal control system in connection with the [**REDACTED**]. The internal control consultant has conducted a review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system

control management and other procedures for our operations. We had improved our internal control system by adopting and implementing a series of new internal control policies. Going forward, we will continue to regularly review and improve these internal control policies, measures and procedures.

We have also appointed external legal counsels to advise us on compliance matters, such as compliance with the regulatory requirements on clinical R&D, which is also monitored by our regulatory and quality assurance team. Under our whistle-blowing policy, we make our internal reporting channel open and available for our employees to report, on an anonymous basis, any non-compliance incidents and acts, including bribery and corruption. Reported incidents and persons will be investigated and appropriate measures will be taken in response to the findings. We have also established anti-bribery guidelines and compliance requirements. After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations.

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant PRC and U.S. laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

#### Anti-bribery

We maintain strict anti-corruption policies among our employees and distributors. We believe we will be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses are rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable. We will also ensure that future commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

### Conflict of Interest and Non-Competition

Our employee handbook clearly defines the scope of conflicts of interest, including supplier and customer relationships, hospitality and gifts, financial interests and personnel matters. Our employees, including but not limited to our Directors and R&D team members, may not accept monetary, financial or other benefits from business partners, suppliers, consultants and other partners, hold shares in business partners, suppliers, consultants and other partners, have employment relationships with business partners, suppliers, consultants

and other partners, or have business transactions with enterprises owned, controlled, or managed by their family members or relatives. At the same time, employees shall keep confidential information strictly confidential and agree on the definition of confidential information, the content covered, the use of intellectual properties, including but not limited to any transfer of know-hows, acquisition of technologies, and potential breach liabilities.

Our CEO and key members of the R&D team have signed non-competition agreement with us, which prohibits employees from engaging in or directly or indirectly assisting any third party to engage in the same, similar and competitive business activities as our Company for a period of 12 or 24 months from the date of termination of employment. Any of our employees shall not, without prior written approval from our Company, own, manage, operate or control any other entity that competes with our Company.