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OVERVIEW

We are an R&D-driven, dermatology-focused biopharmaceutical company dedicated to developing innovative and 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 11 products and product candidates with significant market potential, targeting the four main sectors of the broader dermatology treatment and care market, namely scalp diseases and care, skin diseases and care, localized adipose accumulation management medication and topical anesthesia. We have successfully marketed two products and 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.

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 management awareness and advancing dermatological therapies. According to the same source, 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 RMB1,039.0 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™ technology platform, we have developed our product portfolio to meet the diverse unmet medical needs of physicians and patients. The CATAME™ 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

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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 and highly differentiated 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 global 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.

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Therapeutic Areas	Candidate	Active Ingredients & Formulation	Indication	Commercial Rights	Pre-Clinical	IND	Phase I	Phase II	Phase III	Registration	Commercialization
Scalp Diseases and Care	CU-40102 ¹	Topical finasteride spray	Androgenetic Alopecia	Greater China							
	CU-40101	Topical small molecule thyroid hormone receptor agonist liminert	Alopecia	Asia							
	CU-40103	Topical minoxidil foam	Alopecia	Global							
	CU-40104	Topical dutasteride agent	Androgenetic Alopecia	Global							
Skin Diseases and Care	CUP-MNDE ²	Topical minoxidil spray	Alopecia	Mainland China							
	CUP-SFJH ³	Topical natural plant extracts serum	Alopecia	Mainland China							
	CU-10201 ⁴	Topical 4% minocycline foam	Acne Vulgaris	Greater China							
Localized Adipose Accumulation Management Medication	CU-10101	Topical novel small molecule agent	Atopic Dermatitis	Greater China, Japan, Korea and SEA							
	CU-10401	Topical tapinarof cream	Psoriasis	Greater China, Japan, Korea and SEA							
Topical Anesthesia	CU-20401 ⁵	Recombinant mutant collagenase	Submental Adipose Accumulation Abdominal Adipose Accumulation	Asia							
	CU-30101	Localized topical lidocaine and tetracaine cream	Surface Dermatologic Operations	Greater China							

★ Denotes Core Product

■ Denotes Key Products

▨ Denotes products in registrational trials in China with pilot commercialization in Lecheng, Hainan

1. CU-40102 is currently in a registrational Phase III trial and a Phase I clinical trial in China and has commenced pilot commercialization in Lecheng, Hainan.
2. CUP-MNDE has been commercialized by its original developer, Laboratoires Bailleul, and we entered into an agreement to obtain the exclusive rights for the distribution and marketing of CUP-MNDE in Mainland China.
3. CUP-SFJH has been commercialized by its original developer, VML, and we entered into an agreement to obtain the exclusive rights for the distribution and marketing of CUP-SFJH in Mainland China.
4. CU-10201 is currently in a registrational Phase III trial in China and has commenced pilot commercialization in Lecheng, Hainan.
5. We have completed Phase I clinical trial for CU-20401 for submental adipose accumulation and expect to initiate a Phase II clinical trial of CU-20401 for submental adipose accumulation in the third quarter of 2023.

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Scalp Diseases and Care

- *Key Product CU-40102.* 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 effective in treating 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 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. CU-40102 is expected to demonstrate superior safety and tolerability by topical application compared to oral form due to lower systemic exposure to finasteride. 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 investigational topical liniment to treat androgenetic alopecia. 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 innovative 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 innovative therapeutic agent effective in promoting hair growth in patients with androgenetic alopecia.
- *CU-40103.* CU-40103 is an investigational 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. According to Frost & Sullivan, the global annual sales of topical minoxidil for the treatment of alopecia reached US\$1,001.7 million in 2021. CU-40103 is expected to adopt a differentiated elegant foam formulation and become an innovative addition to the existing minoxidil tinctures and liniments in the market. It features 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 an investigational topical dutasteride to treat androgenetic alopecia. Although dutasteride has not been approved for androgenetic alopecia in China, it has demonstrated efficacy in treating androgenetic alopecia in multiple randomized, double-blind clinical trials. CU-40104’s innovative 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.

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- *CUP-MNDE*. 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. CUP-MNDE is refreshing to be applied to the scalp by its low concentration propylene glycol formulation technology, 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 is effective in promoting 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 is the best-selling minoxidil brand in terms of volume sold in Italy, Portugal and Belgium in 2021, according to Frost & Sullivan.
- *CUP-SFJH*. CUP-SFJH is a commercialized hair growth serum featuring a non-hormonal formula of efficacious and pure natural plant extracts. CUP-SFJH is used for hair loss prevention and hair quality improvement. With its unique liposome technology, CUP-SFJH can effectively transport nutrients to the root of the hair follicles through the double-layer phospholipid membrane wrapping. CUP-SFJH demonstrated efficacy to improve hair volume and advance hairline after six months of use in a small-scale clinical observation in Europe. CUP-SFJH can also be used in combination with our scalp disease drug products to maintain desired results.

Skin Diseases and Care

- *Key Product CU-10201*. 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. The FDA approved CU-10201 for the treatment of moderate to severe acne vulgaris in the U.S. in 2019. Minocycline exhibits broad-spectrum antibacterial activity. The currently available minocycline products are mostly oral medications. With a topical formulation, CU-10201 is more effective in delivering the drug 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.
- *CU-10101*. CU-10101 is a non-hormonal, small molecule innovative drug targeting atopic dermatitis. 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 avoid 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.

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- *CU-10401*. CU-10401, an aryl hydrocarbon receptor (AhR) targeted non-steroidal small molecule chemical drug in topical form, is a generic tapinarof cream targeting psoriasis currently being developed in pre-clinical stage. 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, and it may also result in skin cancer if not properly administered. Systemic therapies are not able to induce effective clinical responses in all patients and may cause serious side effects including higher risk of severe infection. As a result, there has been significant 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.

Localized Adipose Accumulation Management Medication

- *Core Product CU-20401*. CU-20401 is a potential first-in-class investigational recombinant mutant collagenase that targets reduction in excessive local adipose accumulation after subcutaneous treatment. 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 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. We have completed Phase I clinical trial on human subjects for CU-20401 for submental adipose accumulation and are conducting another Phase I clinical trial for abdominal adipose accumulation. The clinical results showed its favorable efficacy and safety profiles. 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. CU-20401 has the potential to become the first-in-class localized adipose accumulation management medication launched in China.

Topical Anesthesia

- *CU-30101*. CU-30101 is a localized lidocaine and tetracaine compound topical anesthesia cream. 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. According to Frost & Sullivan, CU-30101 has equivalent or even higher concentration of lidocaine and tetracaine active ingredients than all FDA approved topical anesthetics. 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 received the NMPA’s IND approval for CU-30101 in November 2022.

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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 RMB670.5 billion in 2025 and RMB1,039.0 billion in 2030, representing a CAGR of 9.2% 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 innovative 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.

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 innovative product offerings. For example, patients in China with greater attention to quality of life tend to spend more on alopecia and skin treatments, and such treatments usually require continuous application to achieve and maintain desired outcomes. 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. Current imported 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. Innovative and effective products are urgently needed for the growing Chinese population with increasing per capita disposable income.

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We are one of the few players in the broader dermatology treatment and care market in China equipped with fully integrated capabilities, according to Frost & Sullivan. We have a comprehensive product pipeline of 11 products and product candidates, including two marketed products, five clinical-stage and four pre-clinical stage drug candidates to fulfill market demands. Our success is attributable to our fully-integrated capabilities, continuous innovation driven by our customer-centric philosophy and proprietary CATAME™ 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.

Fully-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 innovative, safe and effective therapeutic solutions. We have designed a fully-integrated and 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 innovative 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 global 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 and effective marketing to acquire users and increase customer stickiness.

For manufacturing, we are constructing a commercial-scale GMP factory with three drug product production lines in Jiangsu province. The three production lines comprehensively cover topical cream, ointment, aerosol, and foam products with a planned annual production capacity of approximately five million doses. The site is expected to commence operation in 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.

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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 innovative 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™ 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™ technology platform is a comprehensive platform that facilitates the development of products that cover major types of dermatological diseases. The CATAME™ 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™ 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 and highly differentiated product pipeline of creams, sprays, ointments, aerosol foams and other dosage forms.

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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. As of the Latest Practicable Date, we had obtained six IND approvals and are running 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 innovative, effective, and 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 comprehensive, synergistic and highly differentiated innovative pipeline of 11 products and product candidates within three years of inception, of which five products are in registrational clinical trials.

Comprehensive, Synergistic, and Highly Differentiated Innovative Pipeline Captures Large Market Potential and Unmet Needs

We have designed and assembled a comprehensive, synergistic and differentiated portfolio to target diseases with highly unmet medical needs across the four major dermatological therapeutic areas: scalp diseases and care, skin diseases and care, localized adipose accumulation management medication 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, innovative products with proven pathways or potential first-in-class candidates. We believe that the synergistic effects arising from our diverse product pipeline are maximizing our comparative advantages and solidifying our market position by establishing high entry barriers.

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Scalp Diseases and Care

Currently widely accepted therapies for scalp diseases include minoxidil, finasteride and ciproterone, 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., CU-40102 demonstrated its efficacy and safety in European male adult patients where the data showed that a large percentage of patients receiving CU-40102 treatment improved their hair condition compared to the placebo group. The proportion of patients who developed treatment emergent adverse events in the topical finasteride group was comparable to that in the placebo group but lower than in the oral finasteride 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.

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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, according to Frost & Sullivan.

Our key skin disease 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 has been shown to be effective in the treatment of 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, resulting in better efficacy. In a U.S. Phase III randomized study sponsored by Foamix Pharmaceuticals, Inc., CU-10201 demonstrated statistically significant improvement in inflammatory lesion count at week 12 and consistently reduced inflammatory acne over the 12-week study period. 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 Journey Medical, 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 solodyn, a minocycline hydrochloride drug. 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. We believe CU-10201 holds the possibility of redefining the market landscape of acne vulgaris drugs in China.

Localized Adipose Accumulation Management Medication

Current treatment for localized adipose accumulation includes, among others, localized adipose accumulation management medications, energy-based fat reduction 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, which is expected to reach RMB3,927.1 million in 2030, according to the same source.

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Our Core Product, CU-20401, is a potential first-in-class recombinant mutant collagenase that targets reduction in excessive local adipose accumulation after subcutaneous treatment. CU-20401 adopts an innovative 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 trial suggested CU-20401’s promising safety profiles and preliminary efficacy. The clinical data shows that CU-20401 is effective to reduce excessive adipose accumulation with favorable safety profiles. 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. As a local and minimally invasive treatment, CU-20401 exhibited low systemic drug exposure in blood after subcutaneous treatment. CU-20401 has the potential to become the first localized adipose accumulation management medication approved in China and meet the patient demand for safe and efficacious solutions, according to Frost & Sullivan.

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 in China and both of them are compounds of lidocaine and prilocaine. Our product CU-30101 is a topical anesthetic which has equivalent or even higher concentration of lidocaine and tetracaine active ingredients than all FDA approved topical anesthetics, according to Frost & Sullivan. 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. We believe CU-30101 will 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 with Global Vision and Domestic Experiences

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).

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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.

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 Jiuru, 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.

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STRATEGIES

With our mission of becoming a global leading R&D-driven dermatology platform company, we are committed to providing customers with a comprehensive portfolio of innovative, safe and effective solutions in dermatology treatment and care.

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

Leveraging our integrated capabilities across the entire broader dermatology treatment and care industry, we are dedicated to providing innovative, safe and effective 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.

The continued strengthening and expansion of our CATAME™ 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 innovative 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 effective 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.

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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:

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.

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 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. CU-20401 has the potential to become the first-in-class localized adipose accumulation management medication launched in China.

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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 Multi-layered Ecosystem Coverage and Build Our Commercialization Team

We will continue to expand our multi-layered and multi-dimensional 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 effective 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. 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 or

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customer 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 Global Presence

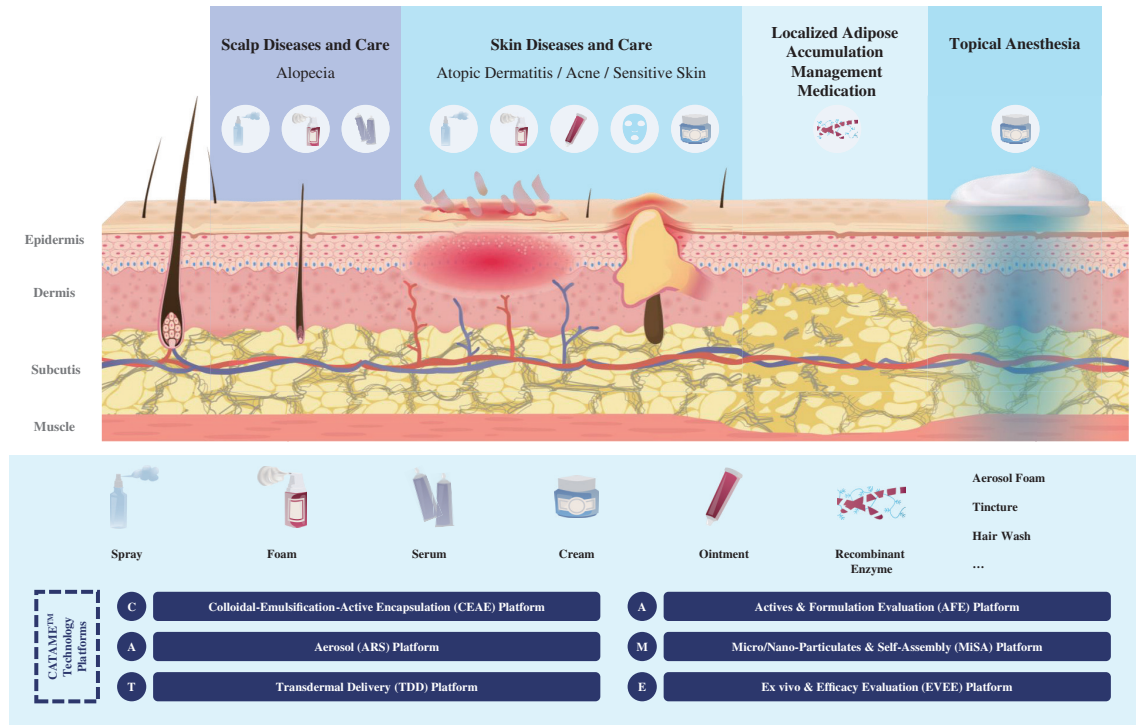
We are committed to becoming a global dermatology platform and improving the quality of life for patients worldwide. We plan to expand into countries and regions with considerable market potential for dermatology solutions based on our resources and commercial readiness. We are well prepared to mitigate 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. We will also seek acquisition or cooperation opportunities with companies with innovative 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.

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PRODUCT CANDIDATES

Our broad portfolio targets the four main sectors of the broader dermatology treatment and care market, namely scalp diseases and care, skin diseases and care, localized adipose accumulation management medication 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 11 products and product candidates. We have successfully marketed two products and 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. The following chart summarizes the development status of our commercialized products, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the Latest Practicable Date:

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Therapeutic Areas	Candidate	Active Ingredients & Formulation	Indication	Commercial Rights	Pre-Clinical	IND	Phase I	Phase II	Phase III	Registration	Commercialization
Scalp Diseases and Care	CU-40102 ¹	Topical finasteride spray	Androgenetic Alopecia	Greater China							
	CU-40101	Topical small molecule thyroid hormone receptor agonist liminert	Alopecia	Asia							
	CU-40103	Topical minoxidil foam	Alopecia	Global							
	CU-40104	Topical dutasteride agent	Androgenetic Alopecia	Global							
Skin Diseases and Care	CUP-MNDE ²	Topical minoxidil spray	Alopecia	Mainland China							
	CUP-SFJH ³	Topical natural plant extracts serum	Alopecia	Mainland China							
	CU-10201 ⁴	Topical 4% minocycline foam	Acne Vulgaris	Greater China							
Localized Adipose Accumulation Management Medication	CU-10101	Topical novel small molecule agent	Atopic Dermatitis	Greater China, Japan, Korea and SEA							
	CU-10401	Topical tapinarof cream	Psoriasis	Greater China, Japan, Korea and SEA							
Topical Anesthesia	CU-20401 ⁵	Recombinant mutant collagenase	Submental Adipose Accumulation Abdominal Adipose Accumulation	Asia							
	CU-30101	Localized topical lidocaine and tetracaine cream	Surface Dermatologic Operations	Greater China							

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

1. CU-40102 is currently in a registrational Phase III trial and a Phase I clinical trial in China and has commenced pilot commercialization in Lecheng, Hainan.
2. CUP-MNDE has been commercialized by its original developer, Laboratoires Bailleul, and we entered into an agreement to obtain the exclusive rights for the distribution and marketing of CUP-MNDE in Mainland China.
3. CUP-SFJH has been commercialized by its original developer, VML, and we entered into an agreement to obtain the exclusive rights for the distribution and marketing of CUP-SFJH in Mainland China.
4. CU-10201 is currently in a registrational Phase III trial in China and has commenced pilot commercialization in Lecheng, Hainan.
5. We have completed Phase I clinical trial for CU-20401 for submental adipose accumulation and expect to initiate a Phase II clinical trial of CU-20401 for submental adipose accumulation in the third quarter of 2023.

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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 effective 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 with severe androgenetic alopecia but it is not applicable for pregnant 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 disease 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, according to Frost & Sullivan. We have formed a comprehensive and synergistic pipeline comprised of six products and product candidates for scalp disease and care, including 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).

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

Overview

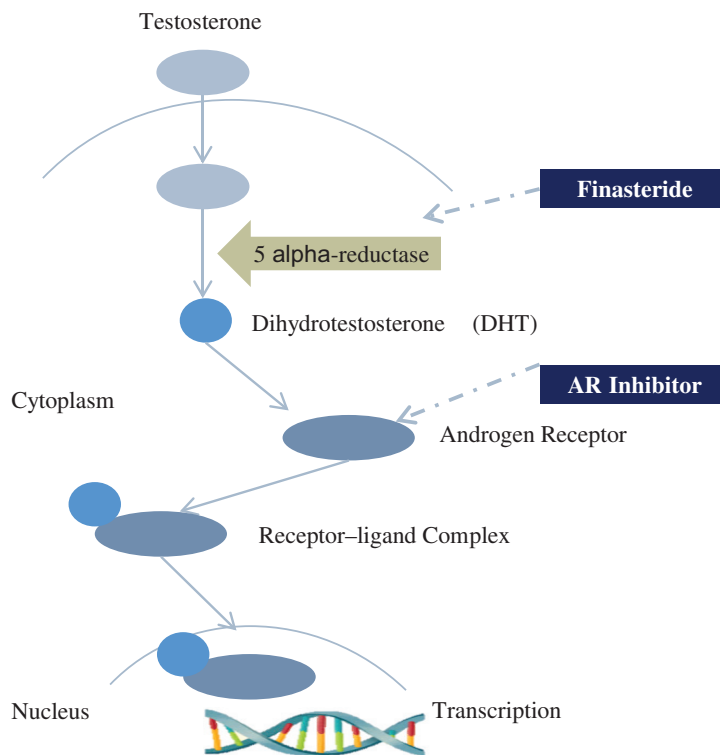
CU-40102 is the first and only topical finasteride product approved for androgenetic alopecia treatment globally and the only topical finasteride under clinical development in China. Finasteride is effective in treating androgenetic alopecia in male patients by acting as a competitive and specific inhibitor of Type II 5-alpha reductase to inhibit the conversion of testosterone to DHT in the scalp. According to Frost & Sullivan, 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%. 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. CU-40102 is expected to demonstrate superior safety and tolerability by topical application compared to oral form due to lower systemic exposure to finasteride. 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 quarter of 2024.

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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

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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 hydroalacquers 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 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 (≤ 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, effectively reduces the serum DHT suppression and reduces the incidence of systemic adverse effects.

Robust Commercial Prospect Supported by Proven Compound and Innovative Formulation

Finasteride as an existing compound has been well trusted by physicians and widely accepted by the market. 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

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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 innovative topical finasteride formulation is applied by spraying onto the scalp. CU-40102 accordingly is expected to effectively 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.

Overview. This was a registrational multi-center, double-blind, randomized, parallel-group, 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.

Trial Design. 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 μ 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.

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

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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 cm² 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, thereby demonstrating the robustness of the primary endpoint. As for the secondary efficacy endpoint, almost all secondary efficacy variables in the CU-40102 group were significantly greater than in the excipient group: the men’s hair growth questionnaire parameter scores (i.e., hair appearance, hair growth, effectiveness in 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

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 androgenetic alopecia in Greater China. For more details about the agreement, see “– Collaboration and Licensing Arrangements – CU-40102 Agreement.”

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Clinical Development Plan

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. 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.

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. The NMPA recommended that we conduct a Phase I clinical trial for a PK study to complement our Phase III clinical trial. We received IND approval for our Phase I and Phase III clinical trial from the NMPA on September 27, 2021. The approval for pilot commercialization of CU-40102 from Hainan Medical Products Administration was received on July 27, 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-40102 SUCCESSFULLY.

CUP-MNDE: Commercialized OTC Minoxidil Spray and CU-40103: Pre-clinical Stage Minoxidil Foam

Overview

CUP-MNDE. 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 by its low concentration propylene glycol formulation, 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 is effective in promoting 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 is the best-selling minoxidil brand in terms of volume sold in Italy, Portugal and Belgium in 2021, according to Frost & Sullivan.

CU-40103. CU-40103 is an investigational topical minoxidil foam for the treatment of alopecia. CU-40103 is expected to adopt a differentiated elegant foam formulation and become an innovative 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

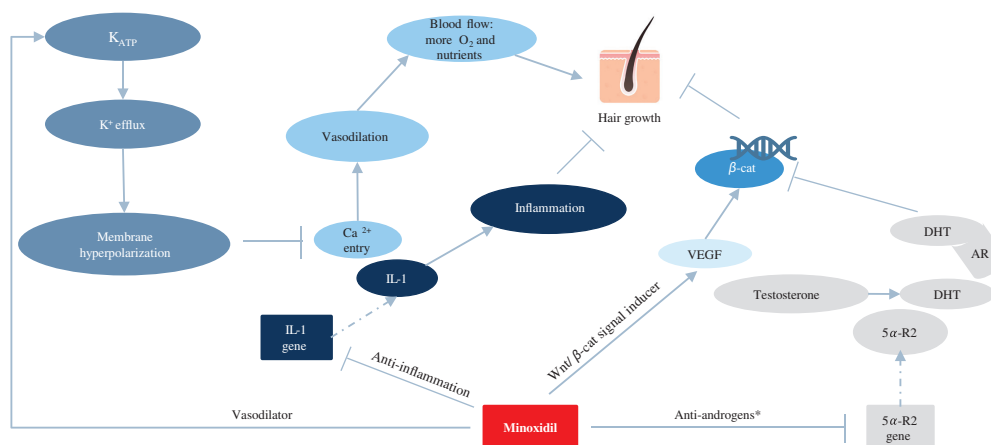
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conducting the pre-clinical study of CU-40103. We plan to submit an ANDA for alopecia to the NMPA in the third quarter of 2024. We believe that CU-40103 has the potential to capture enormous commercial benefit from its differentiated dosage form as 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 CUP-MNDE and CU-40103:



Abbreviations: K: potassium; IL: interleukin; Ca: calcium; O₂: oxygen; VEGF: vascular endothelial growth factor; Wnt: wingless-related integration site; β-cat: beta-catenin; 5α-R2: 5 alpha-reductase; DHT: dihydrotestosterone; AR: androgen receptor

Source: Frost & Sullivan analysis

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Competitive Advantages

We believe that CUP-MNDE and CU-40103 have the following advantages:

Promoting Hair Growth through Innovative Formulation and Enhanced Follicular Delivery

Compared to other topical forms, our minoxidil spray CUP-MNDE improves the solubility of minoxidil, which facilitates the sustained absorption of the active ingredient on the scalp to ensure accurate dosing and enhance transdermal penetration and follicular delivery. In addition, CU-40103 is a topical minoxidil foam, with the advantages of no dripping upon dispensing and easy to apply.

Hypoallergenic Formulation to Scalp and Reduced Adverse Effects (CUP-MNDE only)

CUP-MNDE employs a low concentration propylene glycol formulation technology that is less irritant and hypoallergenic to scalp. Propylene glycol is a common component of topical minoxidil products on the market. However, it is also a contact allergen that can occasionally cause immune contact urticaria and a skin irritant that may cause skin irritation and inflammation particularly in winter, especially for atopic subjects. The higher the concentration of propylene glycol, the greater the risk of allergy and irritation. Additionally, the presence of a high concentration of propylene glycol is also not typically appreciated by users because it renders a product oily and gives a “sticky” appearance to the hair and an unpleasant sensation to the touch. Thus, it is necessary to reduce the concentration of propylene glycol in minoxidil formulations. CUP-MNDE has lower propylene glycol concentration (20%) than the products with propylene glycol concentration of 56% marketed by competing companies, but maintains similar concentration of minoxidil in the dermis after application as compared to a competing product with higher propylene glycol concentration. A skin testing showed that with the unique formulation, CUP-MNDE causes less adverse effects such as skin irritation and allergy and improves the satisfaction of use and patient compliance. The superior safety profile and user satisfaction in texture gives CUP-MNDE potential advantages in clinical use.

Distribution

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. For more details, see “– Collaboration and Licensing Arrangements – CUP-MNDE Agreement.”

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CUP-MNDE and CU-40103 SUCCESSFULLY.

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

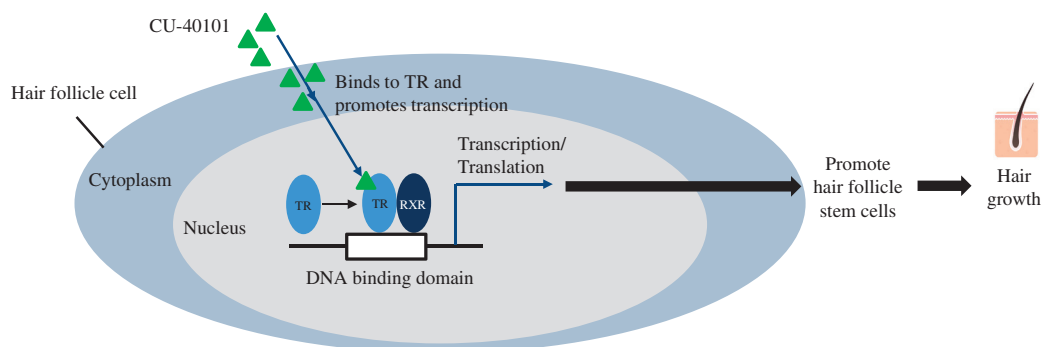
Overview

CU-40101 is an investigational topical liniment to treat androgenetic alopecia. 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 innovative 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 innovative therapeutic agent effective 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 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. Therefore, CU-40101 may be a novel, effective and safe therapeutic agent for the androgenetic alopecia.

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



Source: Frost & Sullivan analysis

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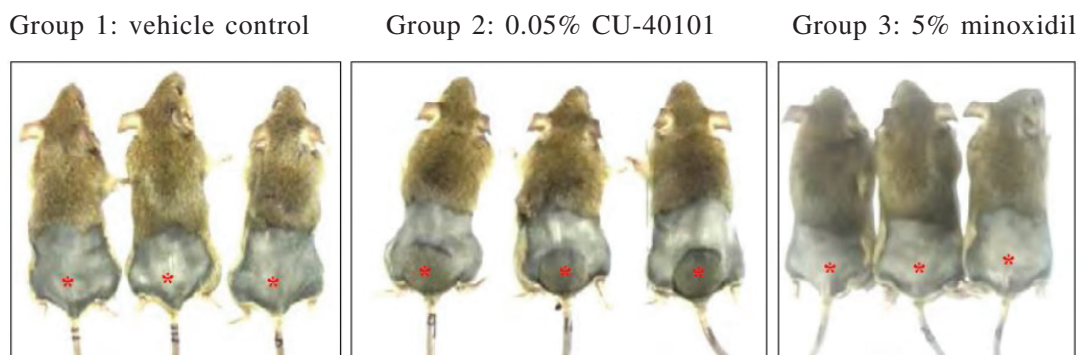
Competitive Advantages

We believe that CU-40101 has the following advantages:

Stimulating Growth of Hair Follicles in Resting Phase

The pre-clinical *in vivo* efficacy studies in C3H mice have shown that CU-40101 is effective in stimulating growth of hair in resting phase in a dose-dependent manner when applied topically. Such results demonstrated the efficacy of CU-40101 in promoting the transition of dormant hair follicles from resting phase to growing phase. In the *in vivo* hair growth model in C3H mice, the hairs on the dorsal skin of C3H mice are in resting phase from about 6-14 weeks after birth. In the pre-clinical *in vivo* efficacy studies, 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. The figure below shows the gross appearance of representative mice in each group on the day 21 of treatment with the red asterisks indicating the center of the treated area. Application of CU-40101 to the dorsal skin of C3H mice induced hair growth prior to the next natural growth phase, presumably by activating hair follicles in resting phase into the growth phase. No significant treatment-related abnormalities were observed during the treatment. 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.

The effects of CU-40101 on growth of hair in resting phase



Source: Company data

Furthermore, treatment for hairs in resting phase of C3H mice with three different concentrations (0.005%, 0.01%, 0.05% w/v) of CU-40101 showed that both 0.01% and 0.05% CU-40101 treatment groups started to grow hair after 3-5 days of administration. In contrast, 0.005% CU-40101 did not show signs of hair growth until 12 days after administration, with

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a delay in reaching full hair. Thus, topical administration of CU-40101 to C3H mice was able to effectively stimulate hair growth in resting phase in a dose-dependent manner, suggesting a potentially novel, effective and safe therapeutic agent for androgenetic alopecia.

Favorable Safety Profile and 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 *in vitro* and *in vivo* genotoxicity studies further showed negative results, sufficient to demonstrate that the compound does not pose a significant risk of genotoxicity. In addition, with a topical liniment formulation, CU-40101 is applied to the scalp directly and is poorly absorbed systemically with a short elimination half-life to reduce the systemic adverse effects or drug-drug interaction. 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. With such extremely low systemic exposure following topical application, the risk of CU-40101 to cause clinical drug-drug interaction is expected to be very low. It is an important advantage for patients to use CU-40101 in combination with other therapeutic drugs concomitantly.

Applicable to Female Patients

The completed pre-clinical studies support that CU-40101 can potentially be used in both male and female patients, in contrast with finasteride, which can only be used in male patients. Although male and female androgenetic alopecia patients have similar etiologies, some safety concerns of finasteride in female patients, especially in pregnant women, have been demonstrated in animal studies and clinical trials. As a result, finasteride is currently not indicated for use in female patients. CU-40101 has a different mechanism of action from finasteride, and based on current animal study results, no special safety signal has been detected in female animals. CU-40101 accordingly has the potential to be further developed to be used in female patients.

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 indications, including scalp disease treatment. 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

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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 an investigational topical dutasteride to treat androgenetic alopecia. Although dutasteride has not been approved for androgenetic alopecia in China, it has demonstrated efficacy in treating androgenetic alopecia in multiple randomized, double-blind clinical trials. CU-40104's innovative 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. We 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.

CUP-SFJH: Commercialized Hair Growth Serum

CUP-SFJH is a commercialized, hair growth serum featuring a non-hormonal formula of efficacious and pure natural plant extracts. CUP-SFJH is used for hair loss prevention and hair quality improvement. With its unique liposome technology, CUP-SFJH can effectively transport nutrients to the root of the hair follicles through the double-layer phospholipid membrane wrapping. CUP-SFJH demonstrated efficacy to improve hair volume and advance hairline after six months of use in a small-scale clinical observation in Europe. CUP-SFJH can also be used in combination with our scalp disease drug products to maintain desired results and reduce side effects.

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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 the Mainland China for CUP-SFJH. For more details, see “– Collaboration and Licensing Arrangements – CUP-SFJH Agreement.”

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 also engage third parties to manufacture and then sell certain skin care products for daily care and post-treatment maintenance in the PRC.

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

Overview

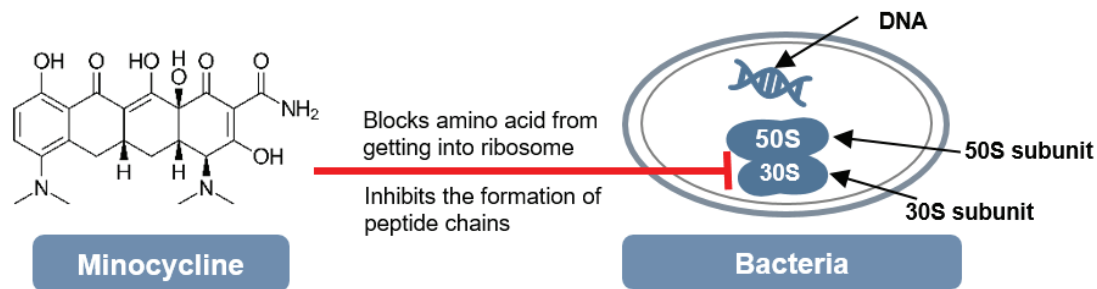
CU-10201 is the first and only topical minocycline approved for acne vulgaris treatment globally. The FDA approved CU-10201 for the treatment of moderate to severe acne vulgaris in the U.S. in 2019. Minocycline exhibits broad-spectrum antibacterial activity. The currently available minocycline products are primarily oral medications. With a topical formulation, CU-10201 is more effective in delivering the drug 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 α /INF- γ and downregulating pro-inflammatory cytokine secretion to inhibit apoptosis.

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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.

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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 has been shown to be effective in the treatment of 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, resulting in more targeted and better efficacy. We believe CU-10201 holds the possibility of redefining the market landscape of acne vulgaris drugs in China.

Competitive Advantages

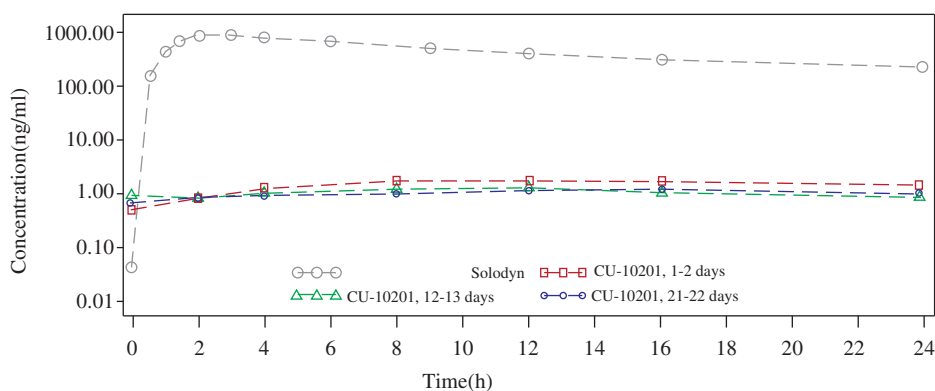
We believe CU-10201 has the following advantages:

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 C_{max}, 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[®] 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

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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, such as *Staphylococcus aureus*, *Streptococcus spp.*, *Pseudomonas aeruginosa* and methicillin-resistant strains of *Staphylococcus epidermidis*. The following table showed the inhibition diameter of the *in vitro* antibacterial activity study. CU-10201 has the largest inhibition of diameter against all the above-mentioned bacteria strains among CU-10201, solvent (placebo) and fucidin. Fucidin is a topical antibiotic commonly used to treat inflammatory lesions in acne vulgaris and other bacterial skin infections.

Antibacterial activity *in vitro*: to compare CU-10201, Fucidin (fusidic acid) ointment and solvent – inhibition of diameter

Bacteria	CU-10201 Inhibition of diameter	Solvent Inhibition of diameter	Fucidin Inhibition of diameter
<i>Staphylococcus aureus</i> 6538	>40, >40, >40 mm	13, 21, 20 mm	>40, >40, >40 mm
<i>Pseudomonas aeruginosa</i> 9027	40, 40, 40 mm	0, 0, 0 mm	11, 12, 16 mm
<i>Staphylococcus</i> (MRSA) 43300	>40, >40, >40 mm	17, 18, 20 mm	40, 40, 38 mm
<i>S. pyogenes abscess</i> 19615	38, 43, 40 mm	12, 15, 11 mm	10, 12, 22 mm
<i>Acne propionic acid bacillus</i> 1182	32, 30, 35 mm	NA	NA

mm = mm; MRSA = methicillin-resistant staphylococcus aureus; NA = not applicable

Note: inhibition of diameter measured to be 0 = null; and 30 or higher = very effective.

Source: Company data

Based on a MIC₉₀ study using a group of 102 clinical isolated strains of *C. acnes* with germline and genotypic diversity mainly from the U.S., the MIC₉₀ value of CU-10201 was 0.25/0.5 µg/mL. CU-10201 was bacteriostatic against clinical isolated strains of *C. acnes* (n=7). In addition, spontaneous resistance to CU-10201 occurred at a frequency of <1 x 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 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.

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

Overview. This was a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial in patients ≥ 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.

Trial design. 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 non-inflammatory lesion count against the baseline after 12-week treatment and 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).

Trial status. We initiated the trial in April 2021 and 372 patients had been enrolled by 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

Overview. This was a randomized, multi-center, double-blind, solvent-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.

Trial design. The patients were randomized to receive either CU-10201 or solvent 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).

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

Safety data. 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 solvent 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

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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 solvent 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 solvent 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 solvent treatments group, respectively. The treatment with CU-10201 for 12 weeks was more effective than solvent treatment in reducing the number of inflammatory and non-inflammatory acne lesions, and achieved treatment success as evaluated by investigator’s global assessment.

Licensing

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. Foamix later merged into VYNE Therapeutics Inc. in late 2021. 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.”

Clinical Development Plan

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.

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 vulgaris 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.

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

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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 a non-hormonal, small molecule innovative drug targeting atopic dermatitis. 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 avoid 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.

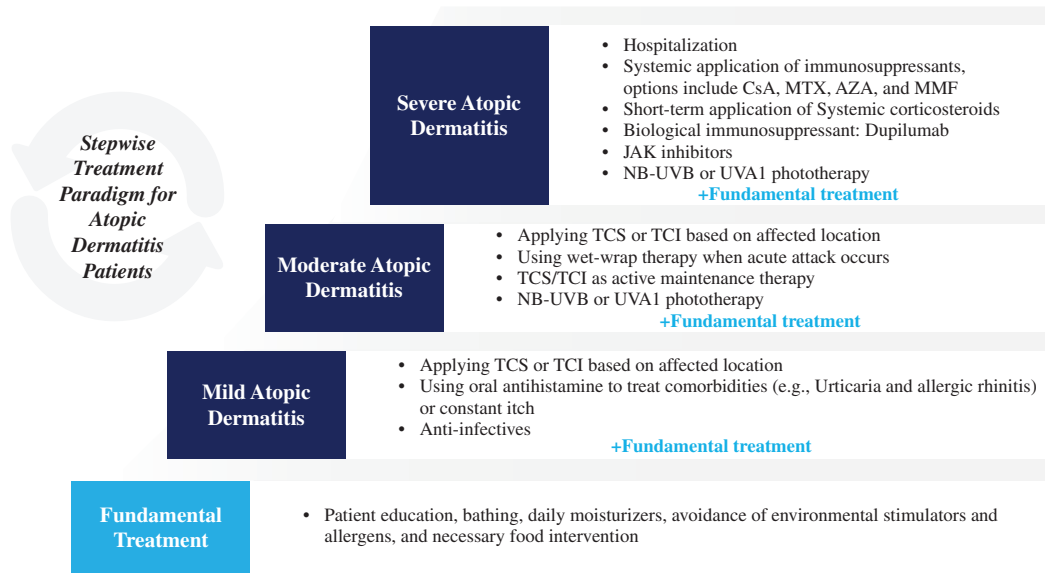
Market Opportunities

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.

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Current Treatment Paradigm and Unmet Clinical Needs

The following figure shows different treatments for atopic dermatitis:



*CsA: cyclosporine A; MTX: methotrexate; AZA: azathioprine; MMF: mycophenolate mofetil; TCS: topical corticosteroids; TCI: topical calcineurin inhibitors

Source: Chinese Society of Dermatology, Frost & Sullivan analysis

The current atopic dermatitis treatment paradigm is facing multiple major challenges, including:

- Insufficient efficacy affecting quality of life and mental wellness:** Atopic dermatitis is a chronic, relapsing skin disorder that has substantial negative impacts on patients' quality of life with social, occupational and academic impairments. Atopic dermatitis requires long-term management such as avoiding triggers, improving skin hydration, managing exacerbating factors, and reducing inflammation. Current medications, however, are unable to offer adequate efficacy and safety, especially for the younger patients who are more prone to mental health issues such as depression and anxiety.
- Concern about side effects:** Topical and systemic medications that are commonly prescribed include corticosteroids and immunosuppressants despite the common side effects from topical steroids such as itching, redness, dryness, skin atrophy, striae, easy bruising and the common side effects from systemic steroids such as weight gain, frequent urination, mood swings, high blood pressure, worsen of diabetes, and higher risks of infections. Common side effects of systemic immunosuppressants include but are not limited to gastrointestinal reactions, allergic reactions, leukopenia, nephrotoxicity, hepatotoxicity, neurological abnormalities, increased risks of carcinoma. The side-effects are a major concern among patients who need to apply corticosteroids and immunosuppressants.

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- *Low penetration of targeted therapy and lack of approved topical targeted drugs:* In China, the number of targeted drugs approved and the adoption of targeted therapies that have demonstrated to bring more clinical benefits than traditional medications in atopic dermatitis is still low. Among the targeted treatments approved, most of them are biologics that need to be subcutaneously injected on a regular basis, which lowers the patients’ willingness to use and compliance with the treatments. Despite the convenience and relatively better patients compliance of topical treatments, there is only one targeted small molecule drug in topical formulation approved for atopic dermatitis in China.
- *Limitations of atopic dermatitis targeted therapies and targeted drugs for mild atopic dermatitis:* Currently, atopic dermatitis targeted drugs such as JAK and IL-4R inhibitors mainly focus on moderate to severe atopic dermatitis treatment. The applications of targeted drugs to treat mild atopic dermatitis are relatively rare. The oral JAK-targeted drugs approved in China and the topical JAK inhibitor approved in the U.S. were warned by the FDA about the potential adverse events such as serious infection, shingles and malignant tumor.

Innovative Solution

The following therapies have emerged as an innovative solution for atopic dermatitis:

- *Innovative targeted therapy:* Atopic dermatitis progression has a complicated mechanism with which multiple proteins are involved, such as IL-4, IL-13, IL-31, IL-33 and TSLP. Some of the pathways are well-developed with target drugs. IL-31 can bind to its receptor on sensory neurons to stimulate the nerves and induce pruritus. Nemolizumab, a humanized monoclonal antibody, can target the IL-31 receptor, showing great efficacy in reduction of pruritus in patients with moderate-to-severe atopic dermatitis, while no significant side-effects were reported in clinical trial. Due to atopic dermatitis patients have higher number of OX40L+, the OX40L-OX40 axis is deemed to be a crucial target for atopic dermatitis treatment. GBR 830 is an inhibitor of OX40 to decrease the expression of OX40 and OX40-L in the lesional skin, while maintain excellent safety and tolerance in Phase IIa clinical trial.
- *Topical targeted small molecules:* Topical targeted drugs of small molecules that can easily pass through skin barrier and target the individual pathways are likely to provide further therapeutic opportunities for patient benefit. Tapinarof cream, a kind of aryl hydrocarbon receptor (AhR) targeted topical therapy, has been approved to treat mild-to-moderate psoriasis in 2019. Currently, the topical use of tapinarof cream for atopic dermatitis has been undergoing Phase III clinical trials in China and it has a great potential to expand its indications to other immune-related diseases. Crisaborole ointment, a kind of PDE4 inhibitor, has been approved to treat atopic dermatitis in 2020. In addition, a number of topical target drug pipelines targeting JAK, PDE4, EGFR, IL-17 have been in clinical trials for the treatment of atopic dermatitis, psoriasis and vitiligo.

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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 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[®]) 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 50 μ M WY14643 (an agonist of peroxisomal proliferation activates receptors) (for positive control group) and 4) 0.0039mg/mL (25 μ L) and 0.001mg/mL (25 μ 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 β , IL-6, TNF α , 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 anti-inflammation 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.

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CU-10401: Pre-clinical Stage Generic Tapinarof Cream

Overview

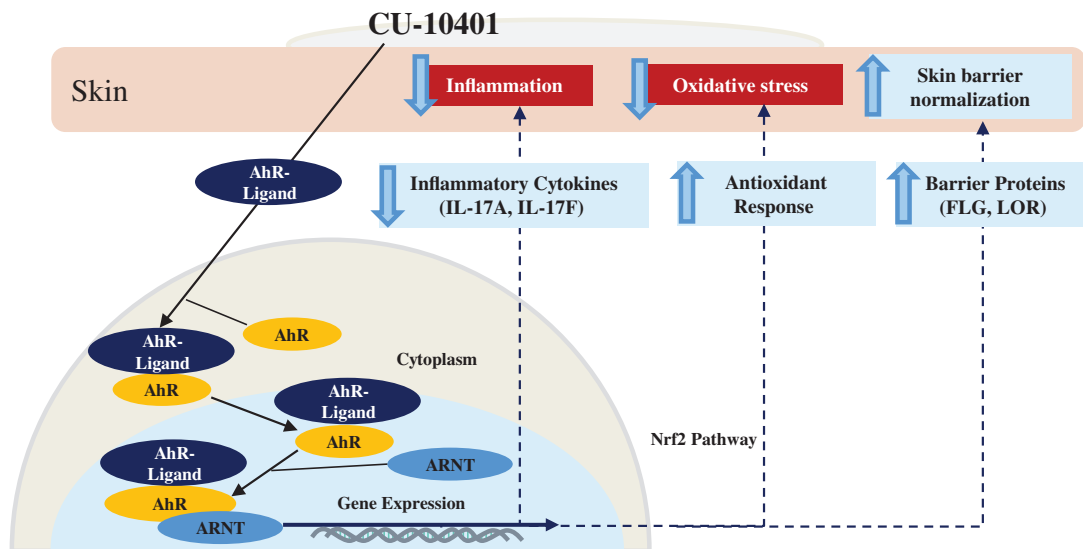
CU-10401, an AhR targeted non-steroidal small molecule chemical drug in topical form, is a generic tapinarof cream targeting psoriasis currently being developed in pre-clinical stage. Current treatments for psoriasis include topical therapy, phototherapy and systemic therapies. Topical treatments are 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, and it may also result in skin cancer if not properly administered. Systemic

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therapies are not able to induce effective clinical responses in all patients and may cause serious side effects including higher risk of severe infection. As a result, there has been significant 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

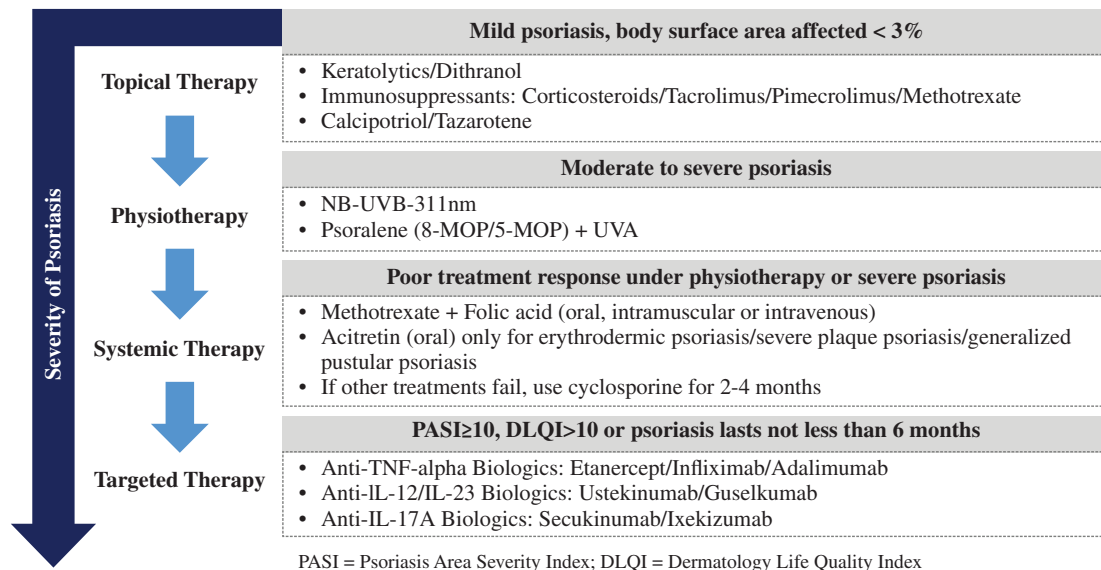
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Market Opportunities and Competitive Advantages

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.

Current Treatment Paradigm and Unmet Clinical Needs

The number of available topical therapies for psoriasis and their efficacy in controlling the disease are both relatively limited; however, most of the systemic medications have significant risk of serious side effects. As a result, treatment choice is made based on the stage and severity of the disease. As the condition worsens, different treatment options can be used alone or combined, including topical, physical, systemic and targeted therapies, as shown below.



Source: Literature review, Frost & Sullivan analysis

Current treatment options for moderate to severe psoriasis patients, or patients with inadequate disease control under currently available topical therapies, are phototherapy and systemic immune modulators, including biotherapeutics that target the T-cell function and that inhibit the activity of TNF-alpha. However, these therapies typically come with one or even more of the following shortcomings including higher cost, inconvenience to administer, serious systemic side effects and even toxicities. Patients are in great demand for a safe, effective, easy-to-use and ideally topical administered innovative therapy.

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Innovative Solution

Tapinarof is the world's first AhR targeted non-steroidal small molecule chemical drug. The AhR is a ligand-dependent transcription factor with roles in the regulation of cytokine and skin-barrier protein expression and antioxidant activity, making it a therapeutic target for the treatment of inflammatory skin diseases and potentially other immunologic diseases. Tapinarof binds to and activates the AhR and has been shown to work by immune modulation, skin-barrier normalization, and antioxidant activity. The Janus kinase-signal transducer and activator of transcription pathway plays a major role in intracellular cytokine signaling in inflammatory processes involved in psoriasis. Although Janus kinase (JAK) 1-3 inhibitors have demonstrated efficacy in patients with moderate-to-severe psoriasis, safety concerns persist and an opportunity exists for novel oral therapies and topical therapies that are safe and efficacious in psoriasis. Tyrosine kinase 2 (TYK2) is a member of the JAK family of kinases and regulates signaling and functional responses downstream of the interleukin 12, interleukin 23, and type I interferon receptors. A deactivating TYK2 genetic variant, driving near-complete loss of function of IL-12, IL-23, and type I IFN signaling, is protective against autoimmunity and does not result in immunodeficiency. Therefore, TYK2 inhibition may be beneficial in the management of psoriasis. Selective, allosteric inhibition of TYK2 signaling may reduce the toxicities associated with pan-JAK inhibitors. Several novel TYK2 inhibitors are in development for moderate-to-severe psoriasis in China.

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.

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LOCALIZED ADIPOSE ACCUMULATION MANAGEMENT MEDICATION

Core Product CU-20401: A Potential First-in-Class Recombinant Mutant Collagenase

Overview

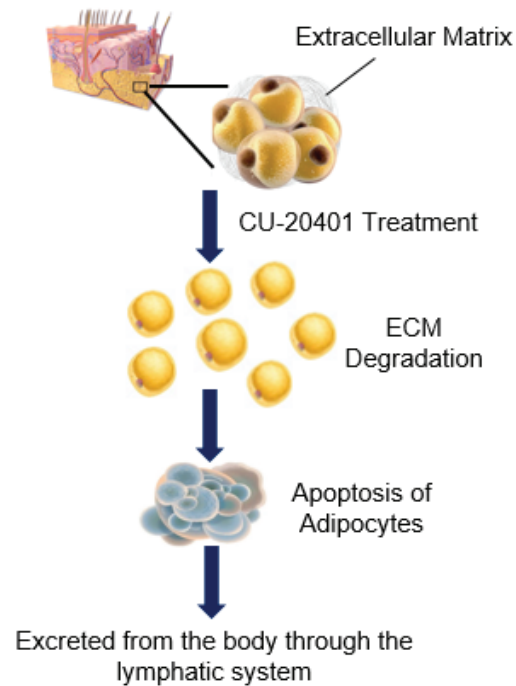
CU-20401 is a potential first-in-class investigational recombinant mutant collagenase that targets reduction in excessive local adipose accumulation after subcutaneous treatment. Fat cells are normally attached to the extracellular matrix composed of collagen network. CU-20401 acts as a collagenase that degrades extracellular matrix collagen in the subcutaneous fat layer, leading to apoptosis of adipocytes. CU-20401 is 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. We have completed Phase I clinical trial of CU-20401 on human subjects for submental adipose accumulation and are conducting another Phase I clinical trial for abdominal adipose accumulation. The clinical results showed its favorable efficacy and safety profiles. 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. CU-20401 has the potential to become the first-in-class localized adipose accumulation management medication launched in China.

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 adipocytes 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, reducing the adverse effects of wild-type collagenase such as bruising and pain.

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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, localized adipose accumulation management medications, energy-based fat reduction 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. 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. Unlike other treatment procedures, localized adipose accumulation management medication product has fewer and milder adverse effects, does not require post-treatment massage or special care and has minimal downtime from normal life routines, which makes it more convenient for patients.

According to Frost & Sullivan, there are currently no approved localized adipose accumulation management medication products and CU-20401 has the potential to be the first approved localized adipose accumulation management medication product in China. We believe that CU-20401 is well-positioned to capture the growth of the localized adipose accumulation management medication market in China, which is expected to reach RMB3,927.1 million in 2030, according to the same source.

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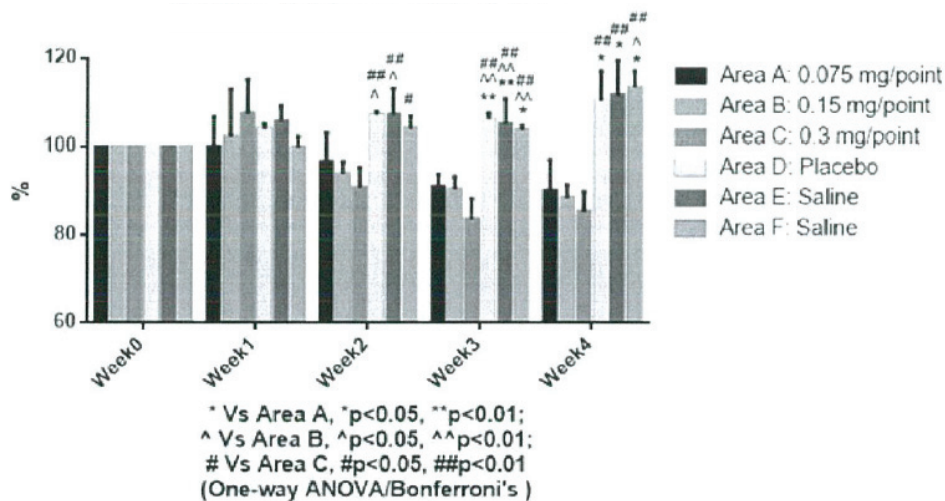
Competitive Advantages

We believe CU-20401 has the following advantages:

Effective in Reducing Adipose Accumulation

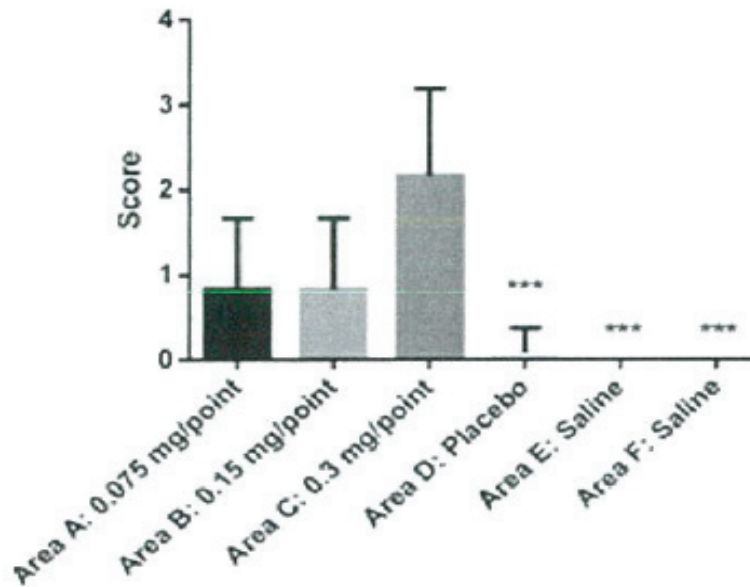
CU-20401 is effective to reduce excessive adipose accumulation in a dose-dependent manner. The pre-clinical animal study used the adipose tissue in the back of Bama mini-pigs to preliminary evaluate the efficacy of CU-20401. The back of Bama mini-pigs was divided to six parallel areas, each of which was subcutaneously injected of placebo, saline, and 0.075 mg, 0.15 mg or 0.3 mg dosages of CU-20401, respectively. The Bama mini-pigs were then examined weekly by ultrasound evaluation. As shown in the below figures, the results demonstrated that CU-20401 administration significantly reduced the thickness of adipose tissue. The dosages of 0.075 mg, 0.15 mg and 0.3 mg of CU-20401 reduced the thickness of adipose layer in Bama mini-pigs by 9.8%, 11.6% and 14.7% in the fourth week after administration, respectively, indicating that CU-20401 functions in a dose-dependent manner. In contrast, the adipose layer thickness in Bama mini-pigs injected with placebo or saline increased by more than 10% due to growing weights during the experiment period. Thus, the results suggested Bama mini-pigs receiving CU-20401 administration had a combined reduction in adipose thickness of more than 20%.

Relative Thickness of Each Area



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Fat Necrosis (0-4)

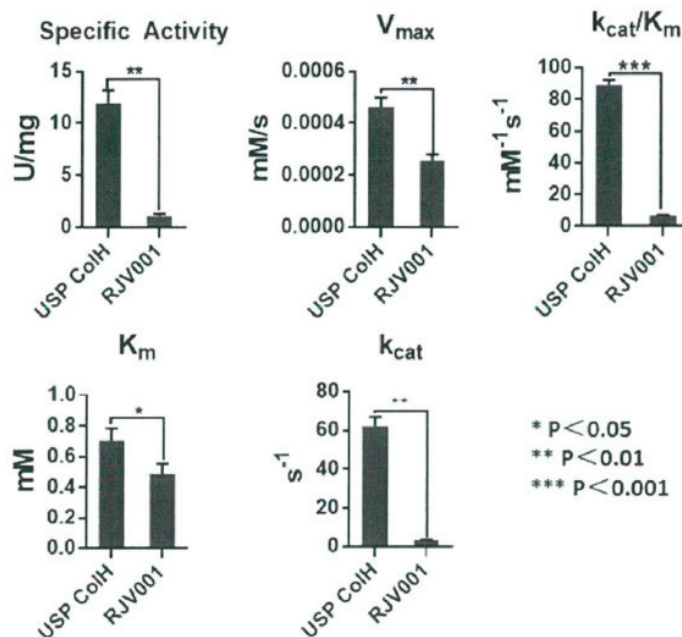


Source: Company data

Gentle Enzyme Activity and Reduced Adverse Effects

As a recombinant mutant collagenase, CU-20401 has similar enzyme affinity to bind substrates but a much lower catalytic rate, compared to the wild-type collagenase. The enzyme activity (collagenolytic activity) of CU-20401 is about 10% of that of the wild-type collagenase. A synthetic peptide “4-phenylazoxycarbonyl-Pro-Leu-Gly-Pro-D-Arg trifluoro acetate” was used as the substrate to determine the enzyme kinetic parameters for United States Pharmacopeia (USP) wild-type collagenase and CU-20401. As demonstrated by the following chart, CU-20401 had a significantly lower catalytic constant K_{cat} (the number of turnover reactions an enzyme catalyzes in unit time) but a comparable Michaelis-Menton constant K_m (the substrate concentration that renders the reaction rate equals to half of the maximum reaction rate, a reflection of enzyme affinity to combine with the substrate). The results indicate that CU-20401 has a comparable affinity to bind the substrate with mild and reduced catalytic activity, which means that it shears collagen more slowly than wild-type collagenase, thereby reducing the adverse effects such as pain, local tissue damage and bleeding.

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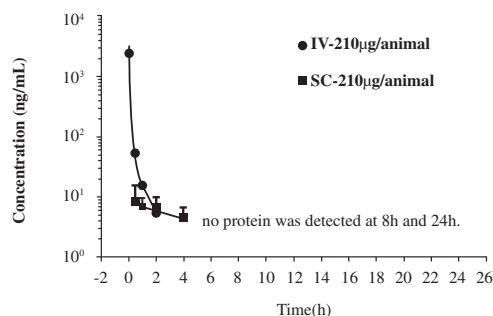
Note: USP ColIH: USP collagenase II; CU-20401 (RVJ001): active pharmaceutical ingredients for pre-test batch of CU-20401

Source: Company data

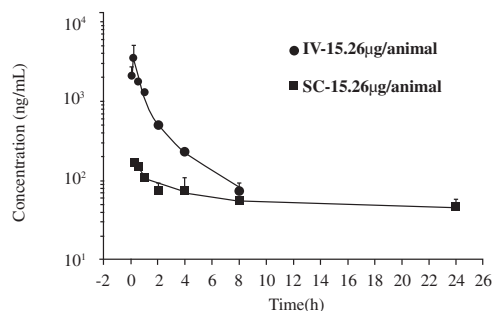
Low Systemic Drug Exposure

CU-20401 exhibited very low systemic drug exposure in blood after subcutaneous or intravenous administration. In a pre-clinical animal study, Sprague Dawley rats and Bama mini-pigs were subcutaneously or intravenously injected with 210 µg per rat and 15.26 mg per mini-pig of CU-20401, respectively, and blood samples were collected via jugular veins. As showed in the following figures, after subcutaneous or intravenous administration of CU-20401, the drug concentration in blood of rats (left figure) and Bama mini-pigs (right figure) declined rapidly. The plasma concentration of CU-20401 in the rats after either subcutaneous or intravenous administration was extremely low and even undetectable at 8 hours and 24 hours post administration. Due to the extremely low systemic drug exposure and rapid clearance, it is impossible to calculate the clearance half-life. Similarly, after subcutaneous administration of CU-20401 in Bama mini-pigs, $T_{1/2}$ and T_{max} were approximately 21.19 hours and 0.25 hours, respectively. Furthermore, because the drug exposure after CU-20401 intravenous administration in the mini-pigs was also extremely low, it was impossible to calculate clearance-related parameters.

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Sprague Dawley rats



Bama mini-pigs

Source: Company data

Summary of Clinical Trial Results

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

Phase I Clinical Trial of CU-20401 for Submental Adipose Accumulation 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 endpoints of the Phase I clinical trial have 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 RP2D of CU-20401 should be 0.06mg/dose or 0.08mg/dose for the subsequent Phase II clinical trial in China.

Trial design. 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) CR-SMFRS to assess the proportion of subjects with submental fact (SMF) Grade ≤ 1 , (ii) SLRS to assess the change in SMF skin laxity from baseline, (iii) PR-SMFRS to assess the change in SMF from baseline, and (iv) SSRS to assess the proportion of subjects with SMF score ≥ 3 .

Cohorts	Formulation (mg)	Dose (ml)	Concentration per dose (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
B1	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

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Trial status. We initiated the trial in February 2022 and completed the Phase I clinical 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 that had already been cured. Only one subject had a sub-Grade 3 TEAE related to CU-20401, namely reduced neutrophil count that had already been cured. 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. In day 28 after CU-20401 treatment, the efficacy profiles among six cohorts are set forth below.

Cohorts	CR-SMFRS	PR-SMFRS	SLRS	SMF Score ≥ 3	Proportion of subjects with at least 10% reduction in SMF from baseline
	proportion of subjects with SMF Grade ≤ 1	decreased from baseline	decreased from baseline		
A1	62.5%	0.5 \pm 0.76	0.1 \pm 0.35	50.0%	0
A2	37.5%	0.8 \pm 0.71	0.1 \pm 0.35	75.0%	12.5%
B1	50.0%	1.3 \pm 0.71	0.1 \pm 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 \pm 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 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 secondary objectives included the parameters of pharmacokinetic and the assessment of immunogenicity of CU-20401 single-dose administration in healthy subjects. We initiated the trial in December 2021 and the trial design was subject to adjustment according to actual needs. As of the Latest Practicable Date, this trial was still actively recruiting subjects with no preliminary clinical results available for analysis.

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Asset Transfer

On August 28, 2020, we entered into an asset transfer 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 potential indications, including adipose accumulation management, cellulite repair, scar modification and other clinical and non-clinical applications. For more details, see “– Collaboration and Licensing Arrangements – CU-20401 Agreement.”

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.

Material Communications with Competent Authorities

We filed an IND application for the Phase I and Phase II clinical trials to assess the safety of CU-20401 in treating submental adipose accumulation to the NMPA in May 2021. We received the IND approval for the Phase I and Phase II clinical trials for submental adipose accumulation in August 2021. According to communications with the CDE, we can proceed with Phase I and Phase II clinical trials so long as we obtain Ethics Committee approval and submit trial design via CDE website, both of which have been completed.

The Phase I clinical trial in China was completed in November 2022 and we, as the sponsor of the trial, and the principal investigators together determined the primary endpoints of the Phase I trial had been reached, and that CU-20401 is safe and well tolerated in subjects with submental adipose accumulation and has demonstrated preliminary efficacy. The RP2D of CU-20401 should be 0.06mg/dose or 0.08mg/dose for the subsequent Phase II clinical trial in China.

Since the primary endpoints of the Phase I 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. As advised by our PRC Legal Advisor and Frost & Sullivan, it is also uncommon for the NMPA to provide an affirmative confirmation or approval as we had obtained its IND approvals from the NMPA for Phase I and Phase II clinical trials. We expect to initiate the Phase II clinical trial in the third quarter of 2023.

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.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CU-20401 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 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. 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. According to Frost & Sullivan, CU-30101 has equivalent or even higher concentration of lidocaine and tetracaine active ingredients than all FDA approved topical anesthetics. 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 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.

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

COLLABORATION AND LICENSING ARRANGEMENTS

CU-20401 Agreement

On August 28, 2020, we entered into an asset transfer 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 term of the CU-20401 Agreement is 20 years from launch of the CU-20401, but we are entitled to continue all development and commercialization activities related to CU-20401 in Asia upon the expiration.

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 potential indications, including but not limited to adipose accumulation management, cellulite repair, scar modification and other clinical and non-clinical applications. 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.

BUSINESS

In consideration of the rights transferred to us, we are required to pay an aggregate of RMB60.0 million in non-refundable upfront fees and development milestone payments. 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-20401 in Asia. As of June 30, 2022, we had paid RMB20.0 million under the CU-20401 Agreement. As of the Latest Practicable Date, we had no intention to out-license CU-20401 in Asia.

An early termination of the CU-20401 Agreement can result from (i) a change in control of a party that materially affects or impedes that party’s performance under the CU-20401 Agreement and the other party gives such party a 60-day prior written notice to terminate the CU-20401 Agreement, (ii) insolvency events, namely 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-20401 Agreement and the breaching party fails to make restitution or cure within 10 days of receipt of a written notice from the other party or within a mutually agreed upon period of time.

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.

Pursuant to the CU-40102 Agreement, Polichem grants to us an exclusive, royalty-bearing, non-assignable and non-sublicensable license regarding the licensed patents, know-how and trademarks and the rights to perform those activities necessary for obtaining the marketing authorization on behalf of Polichem, 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.

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.

In consideration of the licenses and rights granted to us, the down payments and the maximum milestone payments payable by us amount to €13.8 million in the aggregate, which includes €5.3 million down payments and €8.5 million milestone payments consisting of commercial milestone payments. We are also obligated to pay tiered royalties of single digit percentage of annual net sales of CU-40102. As of the Latest Practicable Date, we had paid €4 million under the CU-40102 Agreement.

BUSINESS

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 fail to obtain the marketing authorization in accordance with the timetable; (b) if we fail to comply with the marketing obligation regarding the commercialization of the products; (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 or (e) certain insolvency events.

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 term for the CU-40101 Agreement is 20 years from product launch.

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 indications, including but not limited to scalp disease treatment (the “**CU-40101 Field**”). We will develop, obtain marketing authorization and commercialize CU-40101 at our own costs and expenses and conduct commercialized activities in the CU-40101 Field in Asia.

In consideration of the licenses and rights transferred to us, we are required to pay an aggregate of RMB60.0 million in non-refundable upfront fees and development milestone payments. 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 RMB20.0 million under the CU-40101 Agreement.

Unless terminated earlier, the CU-40101 Agreement will continue in full force and effect. An early termination of the CU-40101 Agreement can result from (i) a change in control of a party that materially affects or impedes that party’s performance under the CU-40101 Agreement and the other party gives such party 10 days written notice to terminate the CU-40101 Agreement, (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 upon period of time.

BUSINESS

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, 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. Foamix later merged into VYNE Therapeutics Inc. in late 2021. 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.

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 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 tiered royalties of single digit percentage of annual net sales of CU-10201. As of the Latest Practicable Date, we had paid US\$10.0 million under the CU-10201 Agreement.

Unless terminated earlier, the CU-10201 Agreement shall continue in full force and effect. 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.

BUSINESS

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. 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.

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. 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.

Unless terminated earlier, the CUP-MNDE Agreement will continue in full force and effect in perpetuity. The agreement will be terminated as of right 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. If the minimum purchase obligation is not met by 80% of the stipulated annual purchase volume for two consecutive years, Laboratoires Bailleul will have the right to terminate the agreement unilaterally and attribute liability for the termination to us.

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 the Mainland China 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.

BUSINESS

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. During the first three years of the CUP-SFJH Agreement, we commit to minimum annual volume of purchases of 20, 60 and 100 thousand units in the first, second and third year, respectively.

The CUP-SFJH Agreement has an initial term beginning on September 1, 2021, and ending on December 31, 2024 with automatic renewal thereafter annually unless it is terminated by written notice at least three months before the expiration date of the period underway. 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 failure(s) and/or breaches of contractual obligations.

OUR PLATFORM

We believe that fully-integrated capabilities are critical to our success in global competition. We have established a full capability 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 and industry-leading CATAMETM technology platform is rare on the market and will continue to drive our technology innovation and product development.

Research and Development

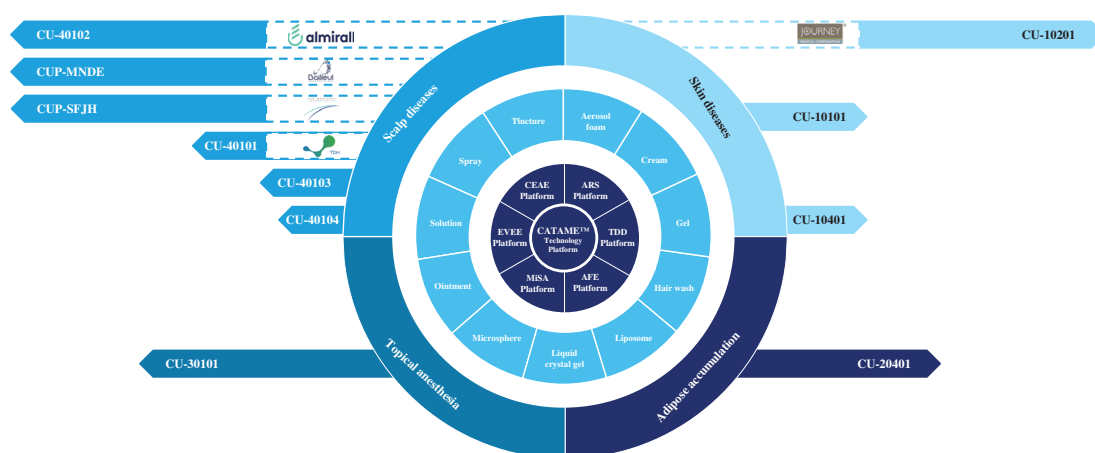
We have developed our clinical and pre-clinical pipeline through a combination of self-development and licensing arrangements. As of the Latest Practicable Date, our R&D team consisted of approximately 32 employees. Our experienced in-house R&D team comes from a variety of medical backgrounds and has 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 2020, 2021 and the six months ended June 30, 2022, our R&D costs of RMB161.9 million, RMB110.6 million and RMB83.5 million, respectively.

BUSINESS

CATAME™ Technology Platform

Our CATAME™ technology platform is an industry-leading, fully integrated R&D platform with high entry barriers. According to Frost & Sullivan, our CATAME™ technology platform, which includes Colloidal-Emulsification-Active Encapsulation (CEAE) platform, Aerosol (ARS) platform, Transdermal Delivery (TDD) platform, Actives & Formulation Evaluation (AFE) platform, Micro/Nano-Particulates & Self-Assembly (MiSA) platform and Ex vivo & Efficacy Evaluation (EVEE) platform, is one of the only few platforms in China that facilitate development of products covering a variety types of dermatological diseases. Our CATAME™ technology platform integrates capabilities to customize transdermal delivery characteristics of drugs, develop micron and nano-sized particulates, evaluate formulation quality and stability and perform cutaneous pharmacokinetic analysis during the development process. The CATAME™ technology platform enables the development of a wide range of product dosage forms and the relevant formulation technology as shown in the chart below. Through the platform, we have built a competitive and highly differentiated 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.

BUSINESS

- *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.

The CATAME™ technology platform helps develop micron and nano-sized particulates, evaluate formulation quality and stability, and cutaneous pharmacokinetic analysis. Based on the CATAME™ technology platform, we have also successfully provided customers a comprehensive, competitive and highly differentiated product pipeline consisting of multiple candidates in various dosage forms. Our platform also helps design the most suitable product formats that are key to specific and successful drug delivery.

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.

Clinical Development

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 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.

BUSINESS

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 or SMOs, 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 and SMOs

We collaborate with CROs and SMOs to conduct and support our pre-clinical and clinical studies in line with industry practice. We select our CROs and SMOs 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.

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 and SMOs 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. The work scope of SMO is generally more limited to day-to-day site management. We choose to engage a CRO or SMO based on the complexity and workload of a specific trial. We closely monitor the work of our CROs and SMOs 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 and SMOs 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.

BUSINESS

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

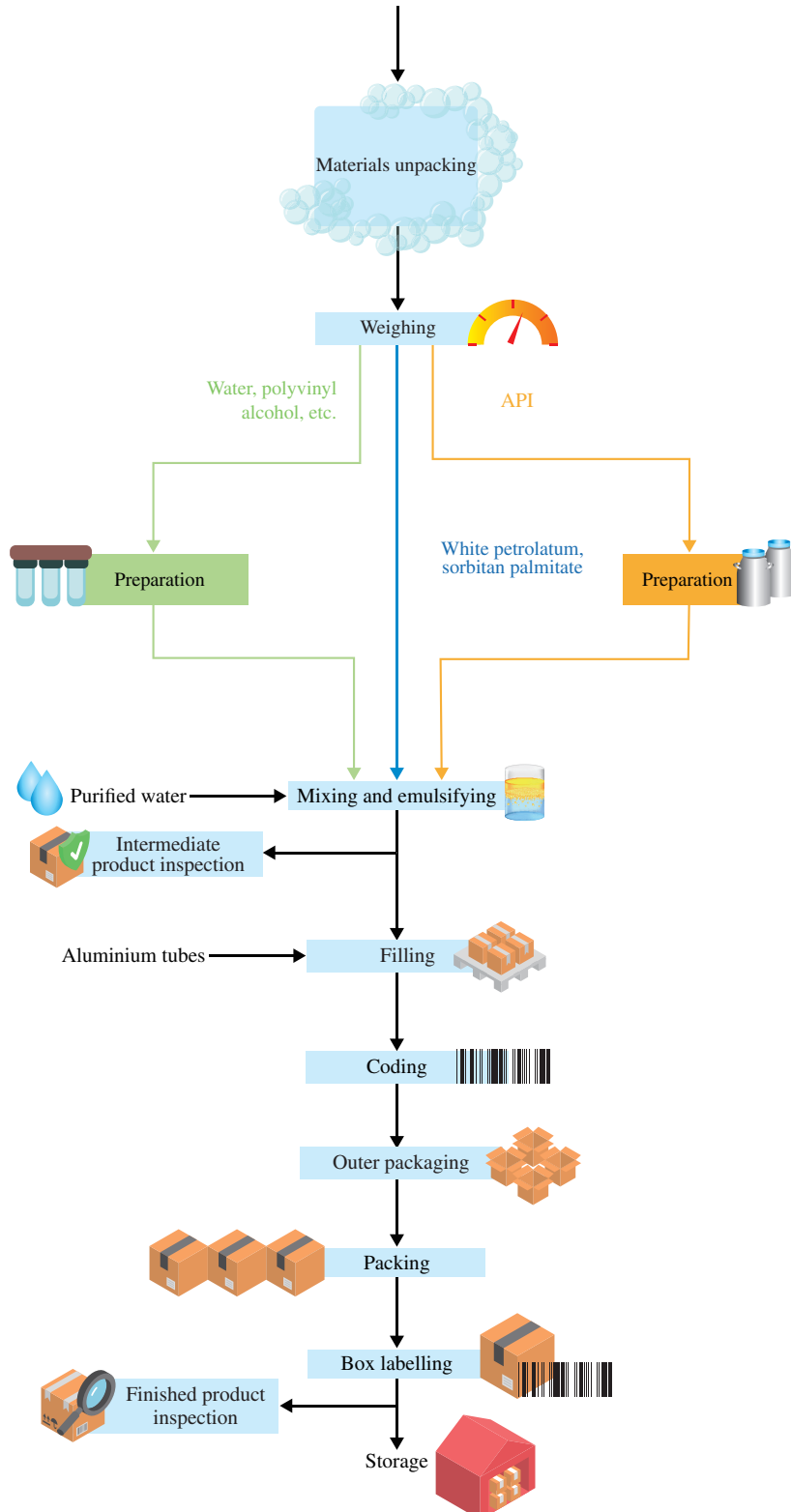
We are constructing three small-molecule formulation commercial-scale manufacturing facilities in Jiangsu province. The facilities will be equipped with three production lines comprehensively covering cream, ointment, aerosol, and foam products with a planned annual production capacity of approximately five million doses. The site is expected to commence operation in 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.

BUSINESS

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

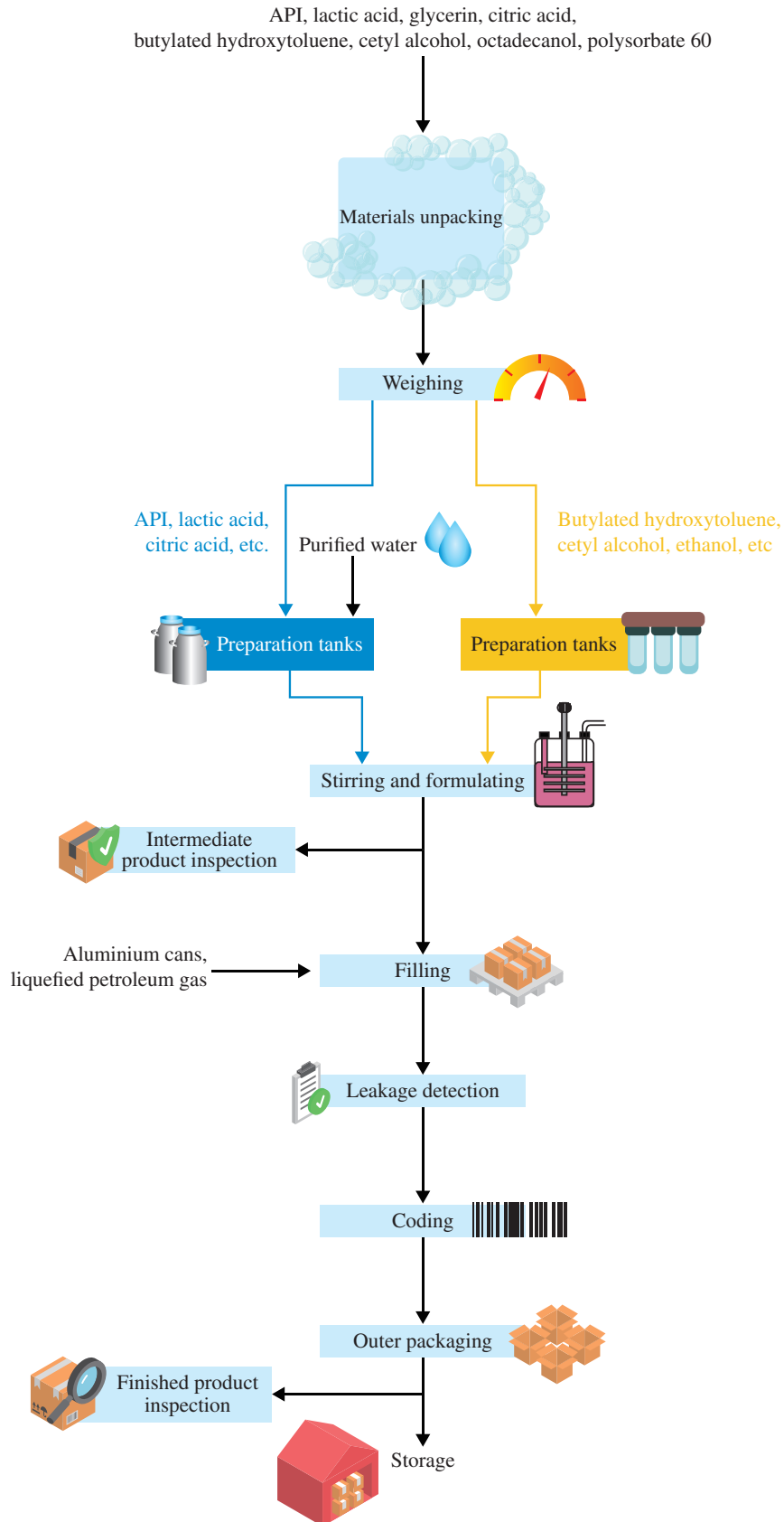
The Manufacturing Process of the Ointment Form

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



BUSINESS

The Manufacturing Process of the Aerosol Foam



BUSINESS

Collaboration with CDMO partners

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.

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.

BUSINESS

Regulatory Affairs

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 operate an integrated commercialization model and we implement our marketing strategy primarily through online channel and offline channels. We plan to sell substantially all of our future commercialize products, including CU-40102 and CU-10201 through online and offline channels in China and overseas markets.

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. 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 KOL engaged by us and may 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.

BUSINESS

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 effectively 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 and CUP-SFJH, to customers through online channel, 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.

Sales to Distributors

We sell CUP-MNDE, CU-40102 and CU-10201 to wholesale distributors. As of the Latest Practicable Date, we had two distributors, both of which are, the 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 e-commerce platform, 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 do not have direct contractual relationships with the sub-distributor.

BUSINESS

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.

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 only had two distributors.

We typically enter into standard distribution agreements, which are sales and purchase agreements in nature, with our distributors with duration of two 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. Our payment terms is generally within 30 days from the agreed date of order or 10 working days from receipt of end-user payment. We only accept returns from distributors in cases where, for example, the product is unsalable or near expiration. 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, particularly in distributing scalp diseases and care products and skin diseases and care products.

We consider various factors in renewing agreements with distributors, including their qualifications, sales and marketing capabilities, sales network, financial resources, customer resources cooperation with us and business development potential. In addition, we proactively manage our distributors to comply with the requirements of relevant laws and regulations. We require our distributors to have sufficient number of quality management personnel, and adequate sales channels resources.

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.

BUSINESS

Prevention of Cannibalization

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

- ***Geographic restrictions.*** 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 two 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.

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 effective 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.

BUSINESS

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.

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 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. Although we believe that the products are eligible for inclusion upon commercialization and meeting criteria of NRDL and NEDL, if we fail to have our products included in the NRDL or NEDL after commercialization, our sales channels may be limited and our revenue from commercial sales will be highly dependent on self-pay patients, which could make our products less competitive. We may need to seek alternatives such as commercial private insurance coverage of our products and need to 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.

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-invoices 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.

BUSINESS

During the Track Record Period, the implementation of the two-invoice system did not have any material impact on our selling prices of products to the distributors.

INTELLECTUAL PROPERTY

Intellectual property 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. 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⁽¹⁾	Market Commercial Rights of the Company
CU-20401	A recombinant variant collagenase preparation method and use thereof	Mainland China	Granted	2038-07-30	Exclusive
CU-40102	Spray dispenser	Mainland China	Pending	N/A	Exclusive ⁽²⁾
CU-40102	Film-forming liquid formulations for drug release to hair and scalp	Hong Kong	Granted	2037-06-30	Exclusive ⁽²⁾
CU-40101	Small molecule compound and synthesizing method and uses thereof	Hong Kong	Granted	2029-07-29	Exclusive ⁽²⁾
CU-40101	Small molecule compound and synthesizing method and uses thereof	Mainland China	Granted	2034-08-14	Exclusive ⁽³⁾
CU-40101	Small molecule compound and synthesizing method and uses thereof	Japan	Granted	2035-08-13	Exclusive ⁽³⁾
CU-10101	A type of diphenylethylene derivative and use thereof	Mainland China	Granted	2033-10-14	Exclusive

BUSINESS

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) We have the exclusive right to use these three patents and patent application in the field relating to androgenic alopecia.
- (3) 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, SMOs, CMOs, CDMOs or other contractors or consultants, may fail or suffer security breaches” in this Document.

BUSINESS

As of the Latest Practicable Date, we owned 99 registered trademarks and filed 50 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.

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. 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.

CUSTOMERS

During the Track Record Period, apart from our two largest customers who are our distributors, our customers are all individual customers. We did not generate any revenue in 2020. The total revenue generated from our two largest customers amounted to RMB381,000 and RMB177,000 in 2021 and the six months ended June 30, 2022, respectively. In 2021 and the six months ended June 30, 2022, our two largest customers together accounted for 18.7% and 26.9%, respectively, of our total revenues during those periods, and our largest customer accounted for 18.7% and 21.1%, respectively, of our total revenues during those periods. We grant a credit term of 10 working days or 30 days to our customers. None of our two largest customers 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, both of our two largest customers 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 during the Track Record Period.

BUSINESS

The tables below set forth certain information about our two largest customers in terms of revenue (in descending order) generated in 2021 and the six months ended June 30, 2022, respectively:

Customer	Years of relationship as of December 31, 2021	Background and business activities	Product sold	Credit term	Sales amount For the year ended December 31, 2021 <i>(RMB'000, except percentages)</i>	Percentage of revenue
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%
Customer	Years of relationship as of June 30, 2022	Background and business activities	Product sold	Credit term	Sales amount For the six months ended June 30, 2022 <i>(RMB'000, except percentages)</i>	Percentage of revenue
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	139	21.1%
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	38	5.8%

BUSINESS

SUPPLIERS

During the Track Record Period, we primarily procured raw materials and equipment to develop and manufacture our product candidates from industry-leading and highly reputable manufacturers and suppliers. Our purchases mainly include third-party contracting services for pre-clinical evaluation and clinical trials of our product candidates and raw materials, and equipment. In 2020, 2021 and the six months ended June 30, 2022, our purchases from our five largest suppliers in the aggregate accounted for 83.7%, 59.4% and 63.7% of our total purchases (including value-added tax), respectively, and our purchases from the largest supplier accounted for 38.6%, 28.2% and 25.3% of our total purchases (including value-added tax), respectively.

To the best of our knowledge, all of our five largest suppliers 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 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, SMOs and CDMOs.

- *Services.* The CRO, SMO, 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, SMO 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, SMO, or CDMO according to the payment schedule agreed by the parties.
- *Confidentiality.* We and the CRO, SMO 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.

BUSINESS

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

Supplier	Years of relationship as of December 31, 2020	Credit term	Product or service supplied	Purchase amount For the year ended December 31, 2020 <i>(RMB'000, except percentages)</i>	Percentage of total purchases
Supplier A	One	25-100 days	R&D services; licensing	68,711	38.6%
Polichem S.A.	One	45 days for the first payment and 20 days for remaining payments	R&D services; licensing	33,232	18.7%
Rejuven Dermaceutical Co., Ltd.	One	20 working days	R&D services; asset transfer	20,000	11.2%
TechnoDerma Medicines Inc.	One	20 working days	R&D services; licensing	15,120	8.5%
Supplier B	Two	N/A	Human resources services	11,957	6.7%

BUSINESS

Supplier	Years of relationship as of December 31, 2021	Credit term	Product or service supplied	Purchase amount For the year ended December 31, 2021 <i>(RMB'000, except percentages)</i>	Percentage of total purchases
Supplier B	Three	N/A	Human resources services	34,978	28.2%
Supplier C	One	30 days	R&D services	14,702	11.8%
Supplier D	Three	20 working days	R&D services; licensing	10,000	8.1%
Supplier E	Two	six months for the first payment and one month for remaining payments	R&D services	7,784	6.3%
Hangzhou Tigermed Consulting Co., Ltd.	One	30 days	R&D services	6,232	5.0%

Supplier	Years of relationship as of June 30, 2022	Credit term	Product or service supplied	Purchase amount For the six months ended June 30, 2022 <i>(RMB'000, except percentages)</i>	Percentage of total purchases
Supplier B	Four	N/A	Human resources services	26,614	25.3%
Supplier F	Less than one	45 days	R&D services; licensing	12,644	12.0%
Supplier C	Two	30 days	R&D services	12,548	12.0%
Supplier G	Two	30 working days	Decoration and electrical and mechanical engineering services	10,543	10.0%
Supplier H	Less than one	30 working days	Indoor design and decoration services	4,548	4.3%

BUSINESS

COMPETITIONS

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 fully-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)

BUSINESS

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. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

<u>Function</u>	<u>Number</u>	<u>Percentage of total</u>
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.

BUSINESS

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	June 1, 2022 to May 31, 2023

BUSINESS

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. For environmental matters, we have adopted policies related to (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.

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.

BUSINESS

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. 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	Potential Impacts
Short term (current annual reporting period)	<ul style="list-style-type: none"> • Sustained elevated temperature 	<ul style="list-style-type: none"> • Reduced revenue from damage to assets, disruption to third-party logistic providers or third-party manufacturers
Medium term (one to three years)		<ul style="list-style-type: none"> • Increased operating expenses
Long term (four to ten years)	<ul style="list-style-type: none"> • Change in climate-related regulations • Shifts in customer preferences 	<ul style="list-style-type: none"> • Increased cost of inventories sold due to policy changes • Reduced demand for goods and services

BUSINESS

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	<ul style="list-style-type: none">• Adopt exhaust gas treatment system and install active carbon filters
Greenhouse gas management	<ul style="list-style-type: none">• Increase the use of clean energy• Use energy efficient equipment
Sewage management	<ul style="list-style-type: none">• Install sewage treatment system
Solid waste management	<ul style="list-style-type: none">• 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 waste disposal

BUSINESS

Focus area	Key measures
Energy and resource conservation	<ul style="list-style-type: none">• 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, transportation network and public perception. Our Group will incorporate climate-related 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 the six months ended June 30, 2022, our electricity consumption levels were 765,628.7 kWh and 440,120.2 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 the six months ended June 30, 2022, our water consumption levels were 908.3 m³ and 493.0 m³, respectively.

BUSINESS

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 the six months ended June 30, 2022, our GHG emissions were approximately 445.3 ton of CO₂ equivalent and 261.5 ton of CO₂ 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 the six months ended June 30, 2022, our hazardous waste discharge levels were approximately 11.5 tons and 5.6 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 2020, 2021 and the six months ended June 30, 2022 was approximately RMB4,850, RMB104,080 and RMB49,000, 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.

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.

BUSINESS

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, 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

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Licenses/Permit	Issuing Authority	Grant Date	Expiry Date
Notice of Approval for Clinical Drug Trials (No. 2021LP02037) (<small>((藥物臨床試驗批准通知書)</small> (<small>編號: 2021LP02037))</small>)	NMPA	December 17, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP02038) (<small>((藥物臨床試驗批准通知書)</small> (<small>編號: 2021LP02038))</small>)	NMPA	December 17, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP02039) (<small>((藥物臨床試驗批准通知書)</small> (<small>編號: 2021LP02039))</small>)	NMPA	December 17, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2021LP01219) (<small>((藥物臨床試驗批准通知書)</small> (<small>編號: 2021LP01219))</small>)	NMPA	August 4, 2021	N/A
Notice of Approval for Clinical Drug Trials (No. 2022LP00366) (<small>((藥物臨床試驗批准通知書)</small> (<small>編號: 2022LP00366))</small>)	NMPA	March 7, 2022	N/A
Notice of Approval for Clinical Drug Trials (No. 2022LP01808) (<small>((藥物臨床試驗批准通知書)</small> (<small>編號: 2022LP01808))</small>)	NMPA	November 1, 2022	N/A
Pharmacy and Poisons Ordinance Wholesale Dealer Licence (No. 72/2A/2022) (<small>((藥劑業及毒藥條例批發商牌照)</small> (<small>編號: 72/2A/2022))</small>)	Pharmacy and Poisons Board	October 3, 2022	October 2, 2023

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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.

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;

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- 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 [REDACTED] 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.

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Data Privacy Protection

We have established procedures to protect the confidentiality of patients' data. We usually require our personnel to collect and safeguard personal information in their possession. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel. 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.