This summary aims to give you an overview of the information contained in this Document. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the [REDACTED] of the Stock Exchange under Chapter 18A of the Listing Rules as we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours. In addition, we have incurred significant operating losses since our inception, and we expect to remain loss making in the near term. We had negative net cash flow from operating activities during the Track Record Period and do not intend to pay any dividends in the near future. Your investment decision should be made in light of these considerations.

There are risks associated with any investment. Some of the particular risks in investing in the [REDACTED] are set out in the section headed "Risk Factors" in this Document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED].

## **OVERVIEW**

We are a biotechnology company dedicated to the research and development of drug candidates for the peri-operative space based on our drug delivery platforms and other patented technologies, with a view to extending our coverage to manufacturing and commercialization of the pharmaceutical products we develop. Our product pipeline focuses on non-opioid post-operative pain management, anti-inflammatory pain control, anesthesia and sedation, of which we identify market potential, with an aim to effectively resolving the deficiencies in safety, efficacy or patient experience of the approved drugs currently available on the market. In designing our pipeline, we carefully select our drug candidates and initially placed strategic emphasis on our Core Product, CPL-01. We aim to expedite the development and commercialization process of our drug candidates through strategic and optimal regulatory pathways in the United States and in China with high efficiency, and offer a focused, complementary and differentiated product portfolio to medical professionals and patients around the world. We believe this approach allows us to potentially leverage the 505(b)(2) regulatory pathway of the FDA for each of our drug candidates. As of the Latest Practicable Date, we had one Core Product at clinical stage and two drug candidates at pre-clinical stage.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORE PRODUCT CPL-01 SUCCESSFULLY.

We believe that the peri-operative space represents great market opportunities, driven primarily by the combination of growing market needs and the limitations faced by drugs currently available on the market. The volume of surgery and consequently the demand for peri-operative anesthetics, analgesics and anti-inflammatory drugs are expected to grow, due to the increasing lifespan globally and the continuously improving medical diagnostic technology and service capacity. Additionally, drugs currently available on the market may be

subject to limitations, such as short-acting, limited analgesic potency. In the case of opioid medication, additionally the usage limitation due to opioid related adverse events and possibility of drug addiction. Our target market is global with our current focus specifically on the U.S. and China markets.

Capitalizing on our two technology platforms, namely PG-Depot and ClearSol, we develop new long-acting sustained release drugs on the PG-Depot technology platform and safe injection types for poorly soluble drugs on the ClearSol technology platform, to precisely address the market pain points. As of the Latest Practicable Date, our product pipeline comprised the following:

- CPL-01 (our Core Product), which is a sustained-release injectable formulation of ropivacaine (Naropin®) for long-acting analgesia during the peri-operative period with decreased opioid use and enhanced safety;
- CPL-05, which is a long-acting NSAID for local analgesia and anti-inflammation, featuring sustained release, long-acting effect and improved safety; and
- CPL-07, a new preparation of alfaxalone, which is a neuroactive steroid anesthetic and does not contain Cremophor EL, a formulation vehicle in prior compounds associated with hypersensitivity reactions.

Our CPL-01 is categorized as a "modified new drug" pursuant to the provision of the Section 505(b)(2) guidelines issued by the FDA. The 505(b)(2) regulatory pathway allows the applicant to rely upon data from an approved Reference Listed Drug (RLD) of the FDA that no longer has patent protection or market exclusivity and for which the applicant has not obtained a right of reference in its full safety and effectiveness reports, which makes the 505(b)(2) regulatory pathway a streamlined NDA process. Drug developers who apply through the 505(b)(2) regulatory pathway would be able to reduce time and cost of R&D as well as mitigate risks. We also intend to develop CPL-05 and potentially CPL-07 under the 505(b)(2) regulatory pathway.

The following chart summarizes the development status of each of our drug candidates as of the Latest Practicable Date:

Candidate	Indication	Pre- clinical	Phase I <sup>(1)</sup>	Phase II Phase IIb Phase	e III NDA	NCT No.
CPL-01* Ropivacaine long- acting sustained- release formulation	Long-acting analgesia			(3)	(2)	NCT05813847 NCT05831449
CPL-05 Meloxicam long- acting sustained- release formulation	Analgesic and anti- inflammatory					
CPL-07 Alfaxalone intravenous injection	Anesthesia and sedation					

Notes:

- (1) Given the fact that CPL-01 is being developed to be administered during surgery, and the fact that it would be unethical to do an unnecessary surgery on healthy normal volunteers, a Phase I clinical trial was not performed. In this situation, it is not unusual for the first-in-human trial to be a Phase IIa clinical trial. The completion of the CPL-01 Phase IIa clinical trial is equivalent to completion of one clinical trial on human subjects.
- (2) The trial is a Phase III MRCT covering clinical sites in the United States and China, based on the surgical model of open inguinal herniorrhaphy. We have begun enrolling patients in the United States in April 2023. The approval from the NMPA to proceed to Phase III clinical trial on the same surgical model in China was obtained in June 2023.
- (3) The trial is a Phase III MRCT covering clinical sites in the United States and China, based on the surgical model of bunionectomy. We have begun enrolling patients in the United States in May 2023. The approval from the NMPA to proceed to Phase III clinical trial on the same surgical model in China was obtained in June 2023.
- \* Denotes our Core Product

Led by an experienced management team with a global vision and local insights, we have an efficient R&D team located in the United States and China in close collaboration, with a full range of capabilities covering drug discovery, pre-clinical research and clinical trials. As of the Latest Practicable Date, we had a strong in-house R&D team comprising 35 members. Among them, approximately 24 have experience in the R&D of new drugs, 18 have master's or doctoral degrees and 20 have over 10 years of experiences in the pharmaceutical industry. In addition, we have also assembled a scientific advisory board for CPL-01, CPL-05 and CPL-07, comprising six distinguished members in the pain management field. The scientific advisory board provides constructive guidance on the pre-clinical and clinical studies of the drug candidates from time to time.

# **OUR CORE PRODUCT**

CPL-01, our Core Product, is a sustained-release injectable formulation of ropivacaine (Naropin®). Ropivacaine is a member of the amide class of local anesthetics indicated for the production of local or regional anesthesia for surgery and acute pain management. However, pain after surgery typically persists for approximately three days. Because of the short duration of the effect of the traditional Naropin®, frequent administrations or infusion by catheter are required if protracted local analgesia is required for post-operative pain management. As a result, based on the fomulation of Naropin®, we have applied the CPL Technologies, PG-Depot, in developing CPL-01 to prolong the duration of analgesic effect at local site, which could last for several days after a single local administration.

Our clinical trials for CPL-01 will be conducted in both the United States and China. Our clinical trials for CPL-01 are designed to cover both surgical models of open inguinal herniorrhaphy (involving soft tissues) and bunionectomy (involving bone tissues), to be eligible for a broad labelling of CPL-01. We initiated Phase III clinical trials for CPL-01 in the United States in 2023. As of the Latest Practicable Date, we had enrolled 15 and 11 patients in the United States for Phase III clinical trials for CPL-01 for open inguinal and bunionectomy, respectively. We have also submitted the protocols of Phase III clinical trial to

the NMPA in China based on the results derived from our clinical trials conducted in the United States and obtained the approval from the NMPA in June 2023 to proceed to Phase III clinical trials of CPL-01 in China. We plan to commence our patient enrollment process in China from August 2023.

The main treatment options available in the post-operative pain market include among others, local anesthetics, acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), and opioids. According to Frost & Sullivan, there is no approved ropivacaine long-acting injection globally as of the Latest Practicable Date and CPL-01 is one of the five ropivacaine long-acting analgesic injection drug candidates under clinical trials globally. The following table sets forth details of clinical-stage ropivacaine long-acting analgesic injections in the global market, including China, as of the Latest Practicable Date:

Global Ropivacaine Long-acting Analgesic Injections in Clinical Trials							
Drug	Active Ingredient	Company	Drug Delivery System	Route of Administration	Clinical Phase	First Posted Date	Location
CPL-01	Ropivacaine	Cali Biosciences	PG-Depot	Injection	Ш	2023/4/14/ 2023/6/13	United States/ China
TLC590	Ropivacaine	Taiwan Liposome Company	Liposome	Injection	II/III	2021/12/17	United States
HR18034	Ropivacaine	HengRui Medicine	Liposome	Injection	III	2023/3/15	China
Controlled Release Ropivacaine Injection	Ropivacaine	Xi'an Lipont	Liposome	Injection	П	2022/10/28	China
LY09606	Ropivacaine	Luye Pharma	Liposome	Injection	I	2021/11/23	China

Source: Clinicaltrials.gov, CDE, Frost & Sullivan Report

As of the Latest Practicable Date, there were five approved long-acting analgesics for administration within the surgical site, namely, Pacira Pharmaceuticals's EXPAREL, Innocoll's XARACOLL, Durect's POSIMIR, Heron Therapeutics's ZYNRELEF and HengRui Medicine's Aihengping, and one long-acting intravenous meloxicam, namely, Baudax's ANJESO, in the global market. According to Frost & Sullivan, the ropivacaine long-acting injections market for post-operative analgesia, the addressable market of CPL-01, is expected to grow from US\$39.3 million in 2025 to US\$669.6 million in 2030 globally, representing a CAGR of 76.3%, and grow from RMB178.4 million in 2026 to RMB589.6 million in 2030 in China, representing a CAGR of 34.8%.

# **Core Product Candidate Development Process**

We have been dedicated to all R&D strategy and responsible for all clinical development activities related to CPL-01. As of the Latest Practicable Date, we had a research and development team of 35 members, covering the full life cycle of drug development including formulation, process research, non-clinical and clinical research, clinical operation, quality management, regulatory affair and others. We have carried out substantial R&D work for more than 12 months on CPL-01, primarily including:

- (a) From April 2017 to June 2019, we conducted in-house pre-clinical studies on PD, PK and toxicity of the CPL-01, and achieved favorable results to support the clinical development and our formulation approach. The PD of CPL-01 was evaluated in different models. In a guinea pig pin-prick pain model, CPL-01 exhibited prolonged local anesthetic efficacy as compared with ropivacaine HCI aqueous solution. Multiple PK studies of CPL-01 demonstrated that in rats and minipigs which administered CPL-01 by subcutaneous injection, infiltration and instillation into an abdominal incisional wound, the plasma exposure of ropivacaine increased with increasing ropivacaine dose in a dose-responsive manner. The toxicity of CPL-01 was also evaluated in multiple studies, in which no evidence of significant local or systemic toxicity due to the administration of CPL-01 was found. The successful completion of our PD, PK and toxicity studies is critical for the clinical trials of CPL-01.
- (b) From June 2020 to January 2022, we conducted a series of studies on scale-up production and quality control to establish CMC standards of the drug candidate, CPL-01.
- (c) We submitted to FDA the IND application for CPL-01 in June 2019 and obtained FDA acknowledgement to proceed with the Phase IIa clinical trial in July 2019. We completed the Phase IIa clinical trial in the United States in August 2020. According to a written confirmation from the FDA, the CPL-01 Phase IIa clinical trial is a standalone clinical trial and the completion of the CPL-01 Phase IIa clinical trial is equivalent to completion of one clinical trial on human subjects. In the Phase IIa clinical study, CPL-01 was well tolerated and showed no evidence of local tissue reaction or impairment of wound healing. No subject was assessed as having LAST by the investigator. The majority of TEAEs were those commonly seen with surgery and peri-operative usage of narcotic analgesic medications. CPL-01 showed no negative impact on clinical laboratory results, vital signs, and ECGs. Systemic exposure to ropivacaine was below the LAST limit. The systemic PK results suggested extended release of ropivacaine from CPL-01 into the incision site and this extended release could contribute to an extended analgesic efficacy profile.

- (d) From July 2021 to June 2022, we initiated and completed Phase IIb clinical trial for CPL-01 for open inguinal herniorrhaphy. The primary endpoints have been achieved. The PK of CPL-01 was consistent with the extended-release formulation and CPL-01 was safe and well tolerated. There were no clinically meaningful or dose-dependent safety signal issues.
- (e) From June 2022 to February 2023, we conducted an additional Phase IIb clinical trial for bunionectomy in order to be eligible for a broad labelling for CPL-01. Both the FDA and the NMPA require the analgesic drugs to be tested in different surgical models in order to get a broad label. As such, we have identified appropriate procedures involving both soft tissues and bone tissues for the clinical trials. The primary endpoints have been achieved. There were no clinically meaningful or dose-dependent safety signal issues. The results of this dose-escalation study demonstrate safety and efficacy in this population, and support further development of the 15 mL dose of CPL-01 in bunionectomy in Phase III.
- (f) We initiated the Phase III clinical trial of CPL-01 for open inguinal herniorrhaphy and bunionectomy in the United States in April 2023 and May 2023, respectively. As of the Latest Practicable Date, the Company had enrolled 15 and 11 patients for the Phase III clinical trial of CPL-01 for open inguinal herniorrhaphy and bunionectomy, respectively.
- (g) We submitted the protocols of Phase III clinical trial to the NMPA in China based on the results derived from our clinical trials conducted in the United States and obtained the approval from the NMPA in June 2023 to proceed to Phase III clinical trials of CPL-01 in China.

## OTHER DRUG CANDIDATES

## CPL-05

CPL-05 is a sustained-release form of meloxicam, which is a long-acting NSAID for local analgesia and anti-inflammation, featuring a sustained release delivery system, with a long-acting effect and potentially improved safety. We are establishing animal models for evaluating the PK, pharmacology and toxicology profile of CPL-05. We had a Pre-IND meeting with respect to CPL-05 with the FDA in November 2022 and received the FDA's written response with suggestions on our proposed plan for CMC, non-clinical studies and clinical studies within the same month. As of the Latest Practicable Date, we had started the IND-enabling studies for CPL-05. We plan to file the IND application for CPL-05 with the FDA through the 505(b)(2) regulatory pathway and the NMPA by the third quarter of 2024.

## **CPL-07**

CPL-07 is a new preparation of alfaxalone, which is a neuroactive steroid anesthetic and does not contain Cremophor EL (a formulation vehicle which, in other products, had been associated with hypersensitivity reactions). We had a Pre-IND meeting with respect to CPL-07 with the FDA in November 2022 and received the FDA's written response with suggestions on our proposed plan for IND application, non-clinical studies and clinical studies in December 2022. We plan to file the IND application for CPL-07 with the FDA potentially through the 505(b)(2) regulatory pathway and the NMPA by the first quarter of 2025.

# **OUR TECHNOLOGIES**

# **CPL Technologies**

CPL-01 and CPL-05 were assigned by Latitude to our Group on September 13, 2016 whereas CPL-07 was assigned by Latitude to our Group on May 13, 2021, whereby our Company has obtained the entire right, title and interest in and to the right to file for any intellectual property rights relating to CPL-01, CPL-05 and CPL-07 throughout the world, including any application of the patents, utility models and any registration of designs in the United States and other countries.

In addition, we were granted an exclusive license for two technology platforms with respect to the drug candidates from Latitude, namely, PG-Depot and ClearSol.

The PG-Depot technology platform is a multi-functional parenteral drug delivery platform for long-acting phospholipid gel, which is suitable for applications that require sustained release of small molecules, peptides and proteins for 1 to 7 days by injecting drugs into soft tissues or body cavities to achieve a customizable and long-acting drug release profile. It can be injected through a fine needle up to 28g, and it is easy to manage with an auto-injector or a pen-type injector. It possesses the advantages of safety, stability, simple production and low cost. PG-Depot is deployed for our drug candidates, including CPL-01 and CPL-05.

The ClearSol technology platform is a universal solubility enhancement platform that can be used for injection, ophthalmic, topical and oral preparations, which is suitable for applications in liquid formulations that require highly insoluble small molecules, peptides and proteins drugs or those with limitations in their existing solvents. Such formulations are effective against API insolubility, instability, solvent allergy, low bioavailability of oral formulations, among others, along with other advantages, such as simple production, convenience, stability and safety. The ClearSol can test the solubility of the API by mixing the API with ClearSol formulation. In particular, compared with common formulation, the ClearSol formulation can be diluted in common infusion diluents without precipitation of the API. ClearSol is deployed for CPL-07.

## Cali Technologies

# EFLA (Emulsions for Local Anesthetics)

The EFLA is a formulation technology, including formulation, process, and method of use to provide safe and long-acting emulsions containing a local anesthetics, such as ropivacaine for the treatment of pain, especially post-operative pain management. The EFLA is particularly useful for managing the surgery or trauma-related pain as the EFLA can prolong LA activity for 1 to 5 days after a single injection, thus providing an extended pain relief benefit. To protect our advanced technology, we submitted a provisional patent application and a non-provisional patent application with respect to the EFLA to the USPTO on March 31, 2021 and July 7, 2021, respectively. See "Business – Intellectual Property" for details of the two patent applications.

#### EXCLUSIVE LICENSE OF CPL TECHNOLOGIES FROM LATITUDE

Pursuant to the license agreement, as amended and restated, between Latitude and us, (the "License Agreement"), Latitude granted us a worldwide, exclusive (even to Latitude), fully-paid up, irrevocable, perpetual, royalty-free and sub-licensable license to develop, manufacture, use, store, sell, offer for sale, have sold, distribute, market, promote, import and export, under the PG-Depot and ClearSol technology platforms, in the field the management of peri-operative and post-operative pain in humans for CPL-01, the management of peri-operative and postoperative pain, inflammatory conditions (including arthritis) in humans for CPL-05, and the induction of general anesthesia in humans for CPL-07. In addition, Latitude granted us a worldwide, exclusive, fully-paid up, irrevocable, perpetual, royalty-fee and sub-licensable license to develop, manufacture, use, store, sell, offer for sale, have sold, distribute, market, promote, import and export drug products (each a "New Drug") that has been developed using or otherwise under the PG-Depot and ClearSol technology platforms, other than CPL-01, CPL-05 and CPL-07, subject to certain notification requirements as prescribed in the License Agreement.

We will solely own all right, title, and interest in and to intellectual property rights created by us ("**Improvement**") relating to CPL-01, CPL-05, CPL-07, or any New Drug or both. Specifically, the Improvement includes, but not limited to, the EFLA technology. The License Agreement may be terminated by us with or without cause, and may be terminated by Latitude with cause. Upon termination of the License Agreement all licenses granted under the License Agreement, including all sublicenses granted by us, will automatically terminate with exception as prescribed in the License Agreement.

Save for a one-time payment of US\$3 million which had been paid to Latitude by us on May 25, 2021, Latitude is not entitled to any additional fees, royalties or milestone payments under the License Agreement.

#### NON-EXEMPT CONTINUING CONNECTED TRANSACTION

We have entered into, and are expected to continue, certain transaction that will constitute non-exempt continuing connected transaction of our Company under the Listing Rules upon [REDACTED]. Accordingly, we have applied to the Stock Exchange for[, and the Stock Exchange has granted,] waivers from strict compliance with (i) the announcement, circular and

independent Shareholders' approval requirements under Rule 14A.105 of the Listing Rules; and (ii) the requirement of limiting the term of continuing connected transaction to three years or less under Rule 14A.52 of the Listing Rules. For further details, see "Connected Transaction."

## COMPETITION

The pharmaceutical industries are highly competitive and subject to rapid and significant change. In addition, it is subject to changes in the overall healthcare industry in China and globally. While we believe that our product development experience and R&D capabilities provide us with competitive advantages, we face potential competition from various sources, including international and domestic pharmaceutical companies. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and with any new drugs that may become available in the future.

The active ingredient in CPL-01, ropivacaine hydrochloride, was approved by the FDA in November 2000 as Naropin®, (AstraZeneca L.P.), for the production of local or regional anesthesia for surgery and for acute pain management. There is no approved ropivacaine long-acting injection globally as of the Latest Practicable Date and CPL-01 is one of the five ropivacaine long-acting analgesic injection drug candidates under clinical trials globally, according to Frost & Sullivan. According to the same source, the ropivacaine long-acting injections market for post-operative analgesia, the addressable market of our Core Product, is expected to grow from US\$39.3 million in 2025 to US\$669.6 million in 2030 globally, representing a CAGR of 76.3%, and grow from RMB178.4 million in 2026 to RMB589.6 million in 2030 in China, representing a CAGR of 34.8%. For more details, see "Business – Our Drug Candidates – Our Core Product – Market Opportunity and Competition."

For the addressable market of our other drug candidates, see "Industry Overview."

#### RESEARCH AND DEVELOPMENT

We believe that R&D is key to driving our therapeutic strategy and maintaining our competitiveness in the biotechnology industry. As the R&D progresses, we have expanded our R&D team with personnel with expertise, corresponding to the needs of developing our existing pipeline products. Our research and development function consists of clinical development, drug discovery, and portfolio management departments. Our research and development function is led by Dr. Erol Onel. As of the Latest Practicable Date, our in-house R&D team had 35 members, 24 of whom have experience in the research and development of new drugs, 18 of whom have master's or doctoral degrees, and 20 of whom have over 10 years of experiences in pharmaceutical industry. We have assembled a scientific advisory board to facilitate the research and development of our drug candidates. We comply with the guidelines issued by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) for our research and development.

In anticipation of our increased R&D needs and market opportunities, we plan to continue to enhance our R&D team and efforts in the following aspects:

- continue to develop and implement an aligned strategy to lead and drive greater product portfolio value delivery, with streamlined clinical development operating model and governance; and
- establish mechanisms and abilities to attract, develop and retain medicine development talents in our industry.

We incurred research and development expenses of RMB62.9 million and RMB84.2 million in 2021 and 2022, respectively, of which RMB61.8 million and RMB75.0 million are attributable to our Core Product, respectively, during the same period.

See "Business - Research and Development."

## INTELLECTUAL PROPERTY

Intellectual property is fundamental to our success and competiveness. We rely on a combination of patents, trademarks, copyrights, trade secrets and other proprietary know-how and regulatory exclusivities, as well as contractual protections, to establish and protect our intellectual property rights. We consider the overall protection of our intellectual property rights to be of material value and act to protect these rights from infringement.

As of the Latest Practicable Date we had two granted patents and four patent applications in connection with our drug candidates, with the details below:

No.	Name of the Patent	Туре	Patent Number/Patent Application Number	Related Drug Candidate(s)	Jurisdiction	Patent Holder/ Applicant	Expiration Year*
1.	A kind of homogeneous emulsification equipment <sup>(1)</sup>	Utility Model	ZL202223235093.5	CPL-01	China	Cali Shenzhen	2032
2.	A combined vacuum drying system for products with ultra- low moisture requirements <sup>(1)</sup>	Utility Model	ZL202223288591.6	CPL-01	China	Cali Shenzhen	2032
3.	Emulsions for Local Anesthetics <sup>(2)</sup>	Invention	PCT/US22/21721	CPL-01	PCT	Cali US	N/A**

No.	Name of the Patent	Туре	Patent Number/Patent Application Number	Related Drug Candidate(s)	Jurisdiction	Patent Holder/ Applicant	Expiration Year*
4.	Emulsions for Local Anesthetics <sup>(3)</sup>	Invention	17369369	CPL-01	U.S.	Cali US	N/A**
5.	Ropivacaine/ meloxicam salt monohydrate I crystal form, and its composition, preparation method and application <sup>(4)</sup>	Invention	202211724956.7	CPL-01	China	Cali Shenzhen	N/A**
6.	Bupivacaine meloxicam A crystal form and its monocrystal, its preparation method and application <sup>(5)</sup>	Invention	202211281061.0	CPL-05	China	Cali Shenzhen	N/A**

- \* Patent expiration does not include or consider any applicable patent term extensions.
- \*\* Pending patent application.
- (1) We obtained two utility model patents with respect to the equipment for producing CPL-01.
- (2) We filed a non-provisional patent application with reference to the provisional patent application (No. 63169121) under the Patent Cooperation Treaty (PCT) on March 24, 2022.
- (3) We filed a non-provisional patent application in respect of the method of use patent to the USPTO on July 7, 2021.
- (4) We filed this patent application in respect of the composition, preparation method and application for CPL-01 with the China National Intellectual Property Administration in December 2022.
- (5) We filed this patent application in respect of the composition, preparation method and application for CPL-05 with the China National Intellectual Property Administration in October 2022.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement of, any intellectual property rights that are threatened or pending, in which we may be a claimant or a respondent.

#### RAW MATERIALS AND SUPPLIERS

Our suppliers are primarily reputable CROs and CMOs with whom we collaborate on pre-clinical studies and clinical trials in the United States and China, and raw material suppliers from whom we procure raw materials and equipment for pre-clinical studies and clinical trials. We select our CROs by reviewing a number of factors, including their

qualifications, relevant expertise, geographic proximity, reputation, track record, and terms offered by them. In 2021 and 2022, our purchases from our five largest suppliers in the aggregate accounted for 63.6% and 67.4% of our total purchases, respectively.

See "Business - Raw Materials and Suppliers" for details.

## **CUSTOMERS**

During the Track Record Period and up to the Latest Practicable Date, we had not generated any revenue from product sales and do not expect to generate any revenue from product sales before the commercialization of one or more of our drug candidates.

#### **OUR STRENGTHS**

We believe the following strengths differentiate us from our competitors:

- Carefully-designed portfolio of drug candidates catered to market demands and with optimal regulatory pathways
- Globalized R&D capabilities and synergistic pipeline with a late stage candidate
- Precise market positioning with advanced technology platforms addressing the unmet medical needs
- An experienced management team with a global vision and local insights, and industry-leading investor

See "Business - Our Strengths" for details.

# **OUR STRATEGIES**

We are dedicated to the discovery and development of peri-operative anesthetics, analgesics and anti-inflammatory drug candidates to address market needs and deliver improved patient outcomes and enhanced hospital economics. To achieve our goals, we plan to focus on the following strategies:

- Rapidly advance our clinical trials and studies for existing drug candidates
- Further improve and expand our product pipeline
- Further attract, cultivate and retain R&D talents
- Enhance commercialization capabilities through internal and external efforts

See "Business - Our Strategies" for details.

## **OUR CONTROLLING SHAREHOLDERS**

As of the Latest Practicable Date (assuming Bangzhao's Subscription has been completed), Mr. Lin controlled the exercise of voting rights attached to a total of 588,000,059 Shares held by Cali Nova, his wholly-owned company, representing approximately 50.83% of the issued share capital of our Company. Immediately upon completion of the [REDACTED] (assuming (i) the [REDACTED] becomes unconditional and the [REDACTED] are issued pursuant to the [REDACTED], (ii) the [REDACTED] is not exercised and (iii) Bangzhao's Acquisitions have been completed), Mr. Lin, through Cali Nova, will be entitled to exercise voting rights of approximately [REDACTED] of the issued share capital of our Company.

In addition, as of the Latest Practicable Date (assuming Bangzhao's Subscription has been completed), Mr. Lin controlled the exercise of voting rights attached to a total of 44,217,687 Shares held by Bangzhao, representing approximately 3.82% of the issued share capital of the Company. In addition, upon completion of Bangzhao's Acquisitions, Mr. Lin will control the exercise of voting rights attached to a total of 173,773,629 Shares held by Bangzhao. Bangzhao is a limited liability partnership and, as of the Latest Practicable Date, it had (i) one limited partner, Shenzhen Hongbangsheng, which is a company wholly owned by Mr. Lin and held 99.90% interest in Bangzhao; and (ii) one general partner, Cao Haixia (曹海霞), who is an independent third party of Mr. Lin and held 0.10% interest in Bangzhao. Pursuant to Bangzhao's Partnership Agreement, (i) partners are entitled to vote on resolutions on matters other than the stipulated matters in accordance with their shares in the partnership; and (ii) unanimous consent of the partners is required for stipulated matters, provided that ultimate decision shall be made in accordance with the decision of Shenzhen Hongbangsheng in the event of disagreements between the partners. As such, Mr. Lin, through Shenzhen Hongbangsheng, indirectly controls the exercise of the voting rights attaching to the Shares held by Bangzhao. Immediately upon completion of the [REDACTED] (assuming (i) the [REDACTED] becomes unconditional and the [REDACTED] are issued pursuant to the [REDACTED], (ii) the [REDACTED] is not exercised, and (iii) Bangzhao's Acquisitions have been completed), Mr. Lin, through Bangzhao and Shenzhen Hongbangsheng, will be entitled to exercise voting rights of approximately [REDACTED] of the issued share capital of our Company.

Immediately following the completion of the [REDACTED] (assuming (i) the [REDACTED] becomes unconditional and the [REDACTED] are issued pursuant to the [REDACTED], (ii) the [REDACTED] is not exercised, and (iii) Bangzhao's Acquisitions have been completed), Mr. Lin, Cali Nova, Bangzhao and Shenzhen Hongbangsheng will together be interested in approximately [REDACTED] of the issued share capital of our Company. Therefore, Mr. Lin, Cali Nova, Bangzhao and Shenzhen Hongbangsheng will constitute the Controlling Shareholders upon [REDACTED].

See "History, Reorganization and Development – Our Shareholding Structure and Information about our Shareholders" and "Relationship with the Controlling Shareholders" for further details.

## [REDACTED] INVESTMENTS

We have underwent several [REDACTED] Investments and our [REDACTED] Investors are Dashan, Bangzhao, Hangbang, Bangqin, Changqi and Lishi. Among the [REDACTED] Investors, [REDACTED] in our Company is Dashan, which will hold approximately [REDACTED] of our Company's issued share capital upon completion of the [REDACTED] (assuming (i) the [REDACTED] becomes unconditional and the [REDACTED] are issued pursuant to the [REDACTED], (ii) the [REDACTED] is not exercised, and (iii) Bangzhao's Acquisitions have been completed). See "History, Reorganization and Development – [REDACTED] Investments" for the identities of our [REDACTED] Investors and the key terms of their investments.

## SUMMARY OF KEY FINANCIAL INFORMATION

The following tables set forth summary financial data from our consolidated financial information for the Track Record Period, extracted from the Accountants' Report set out in Appendix I to this Document. The summary financial data sets forth below should be read together with our consolidated financial statements and the accompanying notes, as well as the section headed "Financial Information."

# Selected Components of Consolidated Statements of Loss

The following table sets forth our consolidated statements of loss for the periods indicated, which have been extracted from our consolidated statements of loss set out in the Accountants' Report included in Appendix I to this Document:

	For the year ended December 31,	
	2021	2022
	RMB'000	RMB'000
Other income	_	352
Other gains and losses	_	(280)
Research and development expenses	(62,857)	(84,204)
Administrative expenses	(30,710)	(11,819)
Finance costs	(80)	(179)
[REDACTED]	(15,701)	(7,335)
Loss before tax	(109,348)	(103,465)
Income tax expense		
Loss for the year	(109,348)	(103,465)
Other comprehensive income/(expense) for the year	(2,408)	11,477
Total comprehensive expense for the year	(111,756)	(91,988)

We currently have no products approved for commercial sale and have not generated any revenue from product sales. We incurred an operating loss in each period of the Track Record Period. We recorded net losses of RMB109.3 million and RMB103.5 million in 2021 and 2022, respectively, primarily due to our research and development expenses, administrative expenses and [REDACTED]. We expect to incur an increased amount of expenses in the foreseeable future as we further our pre-clinical research, continue the clinical development of, seek regulatory approval for and manufacture, our drug candidates, launch our pipeline products, and expand our workforce necessary to operate our business.

See "Financial Information – Description of Selected Components of Consolidated Statements of Loss."

#### Selected Items from the Consolidated Statements of Financial Position

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been extracted from the Accountants' Report set out in Appendix I to this Document:

	As of December 31,		
	2021	2022	
	RMB'000	RMB'000	
Total non-current assets	68,340	74,765	
Total current assets	118,353	57,903	
Total current liabilities	61,297	96,808	
Total non-current liability	_	2,452	
Net assets	125,396	33,408	
Share capital	65	65	
Reserves	125,331	33,343	
Total equity	125,396	33,408	

We recorded net current assets of RMB57.1 million and net current liabilities of RMB38.9 million as of December 31, 2021 and 2022, respectively. The change was mainly due to (i) a decrease of our bank balances and cash by 58.6% from RMB112.2 million as of December 31, 2021 to RMB46.5 million as of December 31, 2022, which was used for the expenses of research and development activities; and (ii) an increase of our current liabilities due to related companies by 76.6% from RMB38.4 million as of December 31, 2021 to RMB67.7 million as of December 31, 2022, which was primarily attributable to an increase in amounts due to Shenzhen Hongbangsheng in non-trade nature of RMB31.1 million. As represented by the Directors of the Company, the non-trade amounts due to related parties are unsecured, interest-free and repayable on demand. Pursuant to a deed of loan forgiveness dated June 26,

2023, Shenzhen Hongbangsheng agrees to forgive the remaining balance of non-trade amounts owing and accrued by the Group to Shenzhen Hongbangsheng, such that upon [**REDACTED**], no amounts are owing or payable by the Group to Shenzhen Hongbangsheng.

# Selected Consolidated Cash Flow Statements Data

The following table sets forth our cash flows as of the dates and for the periods indicated:

	As of and for the December	-
	2021	2022
	RMB'000	RMB'000
Operating cash flow before movements in		
working capital	(83,542)	(96,573)
Net cash used in operating activities	(68,517)	(99,620)
Net cash used in investing activities	(23,451)	(1,584)
Net cash from financing activities	186,498	27,600
Net increase/(decrease) in cash and cash		
equivalents	94,530	(73,604)
Cash and cash equivalents at beginning of the		
year	19,277	112,222
Effects of exchange rate changes	(1,585)	7,850
Cash and cash equivalents at end of the year	112,222	46,468

See "Financial Information – Liquidity and Capital Resources – Cash Flows."

During the Track Record Period, we have incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our R&D costs and administrative expenses. During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital requirements through loans from shareholders and/or related parties and capital contributions by our shareholders. We expect to improve our net operating cash outflows position by: (i) reducing cash outflows by taking comprehensive measures to effectively control costs and operating expenses (other than research and development expenses to be in line with our R&D development); (ii) rapidly advancing the commercialization of our drug candidates through the 505(b)(2) regulatory pathway, with the goal to generate revenues from product sales; and (iii) seeking additional funding through [REDACTED] and debt financing, if needed.

The Directors are of the opinion that, taking into account (i) the financial resources available to our Group, including bank balances and cash of RMB10.1 million as of April 30, 2023, the [REDACTED] from the [REDACTED] Investment completed in June 2023 and the estimated [REDACTED] from the [REDACTED], and (ii) our cash burn rate, which is our cash and cash equivalents balance divided by average monthly net cash used in operating activities plus payments for property and equipment and deposits for acquisition of property and equipment, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this Document. Without taking into account the estimated [REDACTED] from the [REDACTED], our Directors believe that we have sufficient working capital for approximately 12 months from the date of this Document.

#### **KEY FINANCIAL RATIOS**

The following table sets forth our key financial ratio as of the dates indicated:

	As of Dec	As of December 31,		
	2021	2022		
Current ratio <sup>(1)</sup>	193.1%	59.8%		

Note:

(1) Current ratio equals current assets divided by current liabilities as of the end of the year.

Current ratio decreased from 193.1% as of December 31, 2021 to 59.8% as of December 31, 2022, as a result of the combined effect of (i) a decrease in current assets primarily attributable to the decrease of bank balance and cash in 2022 to pay for the expenses for research and development activities; and (ii) an increase in current liabilities primarily attributable to the increase in amounts due to related companies.

## **DIVIDENDS**

No dividend was paid or declared by the Company during the Track Record Period, nor has any dividend been proposed subsequent to the end of the Track Record Period. As confirmed by Maples and Calder (Hong Kong) LLP, our legal advisor on Cayman Islands law, under the Cayman Islands law, a company may declare and pay a dividend out of either profits or share premium account (even if it has only historical losses), provided the dividend payment is authorised by the company's memorandum and articles of association and would not result in the company being unable to pay its debts as they fall due in the ordinary course of business. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our Board of Directors and subject to our Articles of Association and the Cayman Companies Act, and will depend on a number of factors, including our future

operations and earnings, capital requirements, overall financial condition and contractual restrictions. No dividend shall be declared or payable except out of our profits, out of the share premium account and reserves lawfully available for distribution.

## [REDACTED] STATISTICS

The statistics in the following table are based on the assumptions that the [REDACTED] has been completed and [REDACTED] Shares are issued pursuant to the [REDACTED].

	Based on an	Based on an
	[REDACTED] of	[REDACTED] of
	[REDACTED] per	[REDACTED] per
	[REDACTED]	[REDACTED]
Market Capitalization of our Shares <sup>(1)</sup> [ <b>REDACTED</b> ] adjusted consolidated	[REDACTED]	[REDACTED]
net tangible assets per Share <sup>(2)</sup>	[REDACTED]	[REDACTED]

Notes:

- (1) The calculation of market capitalization is based on [REDACTED] Shares expected to be in issue immediately upon completion of the [REDACTED], assuming the [REDACTED] is not exercised.
- (2) The [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share is calculated after making the adjustments referred to in "Appendix II [REDACTED] Financial Information" and on the basis that [REDACTED] Shares were in issue assuming the [REDACTED] has been completed on December 31, 2022.

## [REDACTED]

[REDACTED] to be borne by us are estimated to be approximately RMB[REDACTED], accounting for approximately [REDACTED]% of our gross [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per Share and no Shares are issued pursuant to the [REDACTED]. In the year ended December 31, 2021 and 2022, the [REDACTED] charged to profit or loss were RMB15.7 million and RMB7.3 million, respectively, and the issue costs capitalized to deferred [REDACTED] were RMB2.3 million respectively. After December 31, RMB1.5 million, 2022, approximately RMB[REDACTED] million is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] million is expected to be accounted for as a deduction from equity upon [REDACTED]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

## **IMPACT OF THE COVID-19 PANDEMIC**

Since late 2019, COVID-19 has spread rapidly globally. The World Health Organization declared the COVID-19 outbreak as a global pandemic on March 11, 2020. We have employed various measures to mitigate any impact the COVID-19 outbreak may have on our operations in China and the United States, or the development of our drug candidates, including offering personal protection equipment such as masks to our employees, regularly check the body temperature of our employees and closely monitoring their health conditions.

During the Track Record Period and as of the Latest Practicable Date, our financial performance and business operation were not materially and adversely affected by the outbreak of COVID-19 pandemic. Up to the Latest Practicable Date, our clinical trials were all conducted in the United States and were not affected by any city lockdown or restrictions on logistics and transportation. Although the COVID-19 pandemic potentially affects patients' willingness to stay in hospital and there were minor interruptions in patient enrollment, we managed to timely complete patient enrollment with respect to Phase IIb clinical trial of CPL-01. In December 2022, the PRC government at all levels began to lift some of the restrictive measures aimed at controlling the spread of the COVID-19 virus. However, if the virus, in particular the Delta and Omicron variants thereof, further spreads worldwide, we cannot guarantee that the COVID-19 will not further escalate or have a material adverse effect on our business operations. See "Financial Information – Impact of the COVID-19 Pandemic" for details.

## RECENT DEVELOPMENT AND NO MATERIAL ADVERSE CHANGES

## Recent Update in Our Research and Development

We initiated the Phase III clinical trial of CPL-01 for open inguinal herniorrhaphy and bunionectomy in the United States in April 2023 and May 2023, respectively. As of the Latest Practicable Date, the Company had enrolled 15 and 11 patients in the United States for the Phase III clinical trial of CPL-01 for open inguinal herniorrhaphy and bunionectomy, respectively. We have also submitted the protocols of Phase III clinical trial to the NMPA in China based on the results derived from our clinical trials conducted in the United States and obtained the acceptance notice from the NMPA in March 2023. See "Business – Our Drug Candidates – Our Core Product – Research and Development of CPL-01 – (ii) Clinical Trials."

## Recent Development on Rules Relating to Overseas [REDACTED] and [REDACTED]

On February 17, 2023, the CSRC released the Trial Administrative Measures on the Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) (the "Overseas Listing Trial Measures") and five supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas [REDACTED] and [REDACTED] of PRC domestic companies' securities. According to the Overseas Listing Trial Measures, PRC domestic enterprises that seek to [REDACTED] securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedures with the CSRC and submit filing reports, legal opinions and other relevant documents. For more details, see "Regulatory Environment – Overview of Laws and Regulations in the PRC – Regulations on Overseas [REDACTED]".

As advised by our PRC Legal Advisor, the [REDACTED] shall be deemed as an indirect overseas [REDACTED] and [REDACTED] of a PRC domestic enterprise under the Overseas Listing Trial Measures. Therefore, we are required to make the filing with the CSRC with respect to the [REDACTED] within the specific time limit. We will also perform the reporting obligations to the CSRC in the event of occurrence of material events after the [REDACTED] as required. For more details, see "Risk Factors – Risks Relating to the [REDACTED] – The approval, filing and/or other requirements of the CSRC or other PRC governmental authorities may be required in connection with the [REDACTED] under PRC rules, regulations or policies."

## No Material Adverse Changes

After due and careful consideration, our Directors confirm that, up to the date of this Document, there has been no material adverse change in our financial or trading position or prospects since December 31, 2022, being the end date of the periods reported on in Appendix I to this Document, and there has been no event since December 31, 2022 that would materially affect the information as set out in Appendix I to this Document.

#### RISK FACTORS

Our business and the [REDACTED] involve certain risks as set out in the section headed "Risk Factors" in this Document. You should read that section in its entirety carefully before you decide to invest in our Shares. Some of the major risks we face include:

• We have incurred significant net losses since inception. We expect that we will continue to incur net losses for the foreseeable future and we may not be able to achieve or maintain profitability. Potential investors may lose substantially all of their investments in us given the high risks involved in our business.

- If we are unable to obtain and maintain adequate patent and other intellectual property protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our product candidates or technologies would be materially adversely affected.
- Our business and financial prospects depend substantially on the success of our product candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals or achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.
- If the FDA does not conclude that certain of our product candidates, currently CPL-05 and/or CPL-07, satisfy the requirements for the 505(b)(2) regulatory pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.
- We had net cash outflows from our operating activities during the Track Record Period. We may need to obtain additional financing to fund our operations, and financing may not be available on terms acceptable to us, or at all. If we are unable to obtain sufficient financing, we may be unable to complete the development and commercialization of our product candidates.
- If our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our product candidates.
- The manufacturing of pharmaceutical products is a highly exacting and complex process, and our business could suffer if we encounter problems in manufacturing our future products.

## FUTURE PLANS AND [REDACTED]

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

- (a) Approximately HK\$[REDACTED] million (representing [90.0]% of the [REDACTED]) will be used for the development of our product pipeline:
  - Approximately HK\$[REDACTED] million (representing [71.8]% of the [REDACTED]) will be allocated to fund the continuing research and development activities of our Core Product CPL-01.
  - Approximately HK\$[REDACTED] million (representing [18.2]% of the [REDACTED]) will be allocated to fund the development of our other drug candidates.
- (b) Approximately HK\$[REDACTED] million (representing [REDACTED] of the [REDACTED]) will be used for working capital and other general corporate purposes.

For further details, see "Future Plans and [REDACTED]."