

BUSINESS

OVERVIEW

We are a biopharmaceutical company with a self-developed BeyondX Oral MedChem Platform, focusing on the design, discovery, clinical development, and commercialization of orally bioavailable medicines, which goes beyond the chemical space defined by the traditional “Rule of Five” molecules for patients with cancer and autoimmune diseases worldwide.

LP-168 – Our Core Product, an NDA-Stage BTK Inhibitor

Our Core Product, LP-168, is a “**covalent & non-covalent**” BTK inhibitor, with potentials for both oncology and autoimmune diseases. This dual binding mechanism enables LP-168 to eliminate tumor cells with both wild-type and drug-resistant mutant BTK. LP-168 has shown notable clinical benefits in various oncology and autoimmune diseases indications.

- **MCL — NDA submitted in China in May 2025.** LP-168 has achieved higher response rate (ORR: 63.9%) and longer disease control (PFS: 7.4 months) in relapsed/refractory (“R/R”) mantle cell lymphoma (“MCL”) patients. In May 2025, we submitted an NDA application for treating 3L R/R MCL (post BTKi) patients in China. We currently expect to obtain NDA approval by June 2026, based on the customary regulatory review period for comparable drug candidates.
- **DLBCL — BTD designation in China.** Diffuse large B-cell lymphoma (“DLBCL”) is the most common non-Hodgkin lymphoma (“NHL”) subtypes, representing approximately 40% of the total cases. However, due to its marked heterogeneity, complex biology, and treatment resistance, no BTK inhibitor monotherapy or combination had been approved for the treatment of DLBCL. LP-168 has been granted the Breakthrough Therapy Designation (“BTD”) for the treatment of R/R DLBCL.
- **CLL/SLL — US Phase III head to head clinical trial against approved BTK inhibitor underway.** In U.S. clinical trials, LP-168 has also shown benefits in patients with relapsed or refractory chronic lymphocytic leukemia (“CLL”) who were previously treated with BTK inhibitors (post-BTKi R/R CLL) and has successfully advanced into Phase III clinical trial for 2L R/R CLL/SLL (post BTKi) patients.
- **Combination therapy — Potential infusion-free and chemotherapy-free therapy.** We have obtained the IND approval from the NMPA for the combination therapy of LP-168 and LP-108 in mature B-cell neoplasms, making us one of the first companies in China obtaining the IND for a combination therapy of BTK inhibitor and Bcl-2 inhibitor. We expect the combination of LP-168 and LP-108 to deliver deep and durable responses, positioning it as a potential infusion-free and chemotherapy-free combination therapy for multiple B-cell malignancies, such as CLL/SLL and other non-Hodgkin lymphomas.
- **Autoimmune diseases — Significant market potential.** BTK inhibitors also have significant market potential across multiple autoimmune indications, where large patient populations and unmet needs persist despite existing therapies. Clinical trial of LP-168 in chronic spontaneous urticaria (“CSU”) has been initiated in China. In August 2024, we entered into a strategic collaboration with Hansoh Pharma for the research, development, registration, manufacturing and commercialization of LP-168 in non-oncology indications in Chinese mainland, Hong Kong, Macau and Taiwan, with total upfront and milestone payments of up to RMB729 million.

Other Clinical-stage Drug Assets

We also have developed two clinical-stage drug assets leveraging our integrated BeyondX Oral MedChem Platform, namely LP-108 and LP-118.

- **LP-108**, a selective Bcl-2 inhibitor. We plan to initiate the registrational Phase II registrational clinical trial in China for R/R CLL/SLL in the second quarter of 2026. We are also developing the combination therapy of LP-168 and LP-108.
- **LP-118**, an oral dual Bcl-2/Bcl-xL inhibitor. Phase I clinical trial data shows encouraging safety and efficacy profile support broad therapeutic potential across multiple cancer indications in which Bcl-2 and or Bcl-xL plays an important role, such as B-cell malignancy (CLL/SLL, DLBCL, MCL etc), Myelofibrosis, ALL, and SCLC.

BUSINESS

The following pipeline chart depicts our major pipeline products and their respective status as of the Latest Practicable Date.

Platforms	Candidate Drugs	Regimen	Target	Indications	Competent Authority	Preclinical	IND	Phase I	Phase II	Phase III	NDA	Current Status/Milestone	Commercial Rights	Target Jurisdiction	Partners
Covalent/Non-covalent platform	★ LP-168 ^(*)	Mono	BTK	3L R/R MCL (post BTK) ^(*)	NMPA							NDA Submitted ^(*) Expected to receive NDA approval by June 2026	Global	China	
		Mono	BTK	2L+ R/R MCL (BTK naïve)	NMPA							Phase III trial stage	Global	China	
		Mono	BTK	3L+ R/R non-GCB DLBCL (post BTK)	NMPA							Phase II registrational stage	Global	China	
		Mono	BTK	2L+ R/R CLL/SLL (post BTK)	FDA							Phase III clinical trial initiated in January 2026	Global	United States	
		Combo	BTK+R-CHOP	1L DLBCL/MCL/MZL	NMPA							Phase Ib trial stage; Expect to initiate Phase II trial in 2027H1	Global	China	
	BeyondX Oral MedChem Platform	Combo	BTK+CD20	2L+ R/R CLL/SLL	FDA							Phase II trial stage	Global	United States	
		Mono	BTK	2L+ CSU	NMPA							Phase VII trial stage	Global	China	
		Mono	BTK	2L+ ITP	NMPA							Preclinical stage	Global	China ^(*)	 除威制药
		Mono	BTK	pMN	NMPA							Preclinical stage	Global	China ^(*)	
		Mono	BTK	MS	NMPA							Phase II trial stage	Global	China	
PPI platform	LP-108	Mono	Bcl-2	2L+ R/R CLL/SLL	NMPA							Completed Phase I trial; Expect to initiate Phase II registrational trial by June 2026	Global	China	
		Combo	BTK+Bcl-2	2L R/R CLL/SLL	FDA							Phase II trial stage; Expect to enroll patients in 2026H2	Global	United States	
	LP-118	Combo	BTK+Bcl-2	1L&2L+ R/R CLL/SLL	NMPA							IND approved; Expect to initiate Phase III trial by June 2026	Global	China	
		Mono	Bcl-2Bcl-1&L	2L-3L SCLC, 2L+ R/R NHL	NMPA							Completed Phase I trial	Global	China	
		Mono	Bcl-2Bcl-1&L	2L+ R/R Hematologic tumors	FDA							Phase I/IIb trial stage	Global	United States	
PROTAC platform	★ NW-7-354 NW-3-461 NW-22-159	Combo	Bcl-2Bcl-1&L+LCK	2L+ R/R T-ALL/LBL	FDA							Phase I/IIb trial stage	Global	United States	
		PROTAC	BTK	2L+ R/R CLL/SLL, DLBCL	NMPA							Preclinical stage; Expect to submit IND application in 2027H1	Global	China	
		PROTAC	MDM2	2L+ R/R AML	NMPA							Preclinical stage; Expect to submit IND application in 2027H1	Global	China	
★ Core Product	★ NMPA Breakthrough Therapy Designation	PROTAC	KRAS	2L+ R/R NSCLC, CRC, Pancreatic cancer	NMPA							Preclinical stage; Expect to submit IND application in 2027H1	Global	China	

Abbreviations: Mono = monotherapy, Combo = combination therapy, PROTAC = proteolysis targeting chimera, R-CHOP = rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate and prednisone, R/R = relapsed or refractory, MCL = mantle cell lymphoma, DLBCL = diffuse large B cell lymphoma, CLL/SLL = chronic lymphocytic leukemia and small lymphocytic lymphoma, B-NHL = B cell non-Hodgkin lymphoma, TN = triple negative, MZL = marginal zone lymphoma, CSU = chronic spontaneous urticaria, ITP = immune thrombocytopenic purpura, pMN = primary membranous nephropathy, MS = multiple sclerosis, SCLC = small cell lung cancer, T-ALL = T cell acute lymphoblastic leukemia, LBL = lymphoblastic lymphoma, NMPA = National Medical Products Administration, FDA = Food and Drug Administration, NDA = new drug application, IND = investigational new drug.

BUSINESS

Notes:

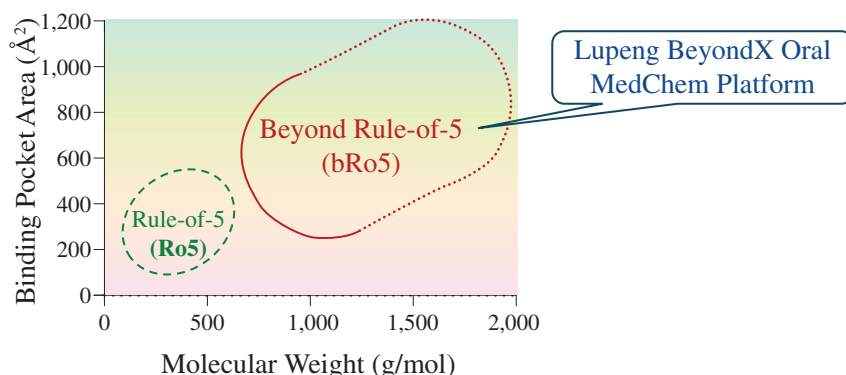
1. We entered into a license agreement with Hansoh Pharma in August 2024, pursuant to which we granted Hansoh Pharma the exclusive right to research, develop, register, manufacture and commercialize LP-168 for non-oncology indications in Chinese mainland, Hong Kong, Macau and Taiwan. For additional information, see “Business — Licensing Agreement.”
2. We reached primary endpoints and completed the MCL cohort of the Phase I clinical trial of LP-168 in China in patients with R/R B-cell lymphoma (NCT05993690) in May 2023. Following its completion, we had a Type II End of Phase I meeting with the Center of Drug Evaluation (“CDE”) of the NMPA in July 2023 and the CDE confirmed that we may proceed with a next-phase single-arm study in patients with R/R MCL who had previously received immunotherapy containing CD20 monoclonal antibody and BTK inhibitors as a registrational Phase II registration clinical study to support its NDA application. We initiated the Phase II clinical trial (NCT05716087) in May 2023 and had reached all the primary endpoints in December 2024. In January 2025, we submitted the six-month follow-up assessment results for this clinical trial to the CDE and the CDE confirmed in a written response in May 2025 that we may proceed with the NDA application for LP-168. Accordingly, we submitted the NDA application for LP-168 for the treatment of R/R MCL to the NMPA in May 2025, which was accepted by the NMPA in the same months. We currently expect to obtain NDA approval by June 2026, based on the customary regulatory review period for comparable drug candidates.
3. Pursuant to the Technical Guidelines for the Applicability of Single-Arm Clinical Trial to Support NDA Applications for Oncology Drugs (單臂臨床試驗用於支持抗腫瘤藥上市申請的適用性技術指導原則) issued by the NMPA in March 2023 (“**March 2023 Technical Guidelines**”), we expect that the NDA for LP-168, if approved by the CDE, will be an NDA subject to the condition that we shall complete, and reach primary endpoints for a randomized and controlled registrational clinical trial; or a single-arm clinical trial in a larger subject group with a longer follow-up review period (“**Additional Registrational Clinical Trial**”). As requested by the CDE pursuant to the March 2023 Technical Guidelines, the Additional Registrational Clinical Trial shall be initiated prior to the granting of the conditional NDA approval. Upon obtaining conditional approval for the treatment of R/R MCL, we will be permitted to commence commercial sales of LP-168. The NDA would allow us to commercialize LP-168 in Chinese Mainland in the third-line or later setting to treat R/R MCL patients who have previously received immunotherapy containing CD20 monoclonal antibody and BTK inhibitor treatment. In January 2026, we initiated a head-to-head Additional Registrational Clinical Trial in China evaluating LP-168 versus approved BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib, or orelabrutinib) for R/R MCL, anticipating enrollment of approximately 394 subjects. In the event that we fail to establish favorable safety and/or efficacy profiles in such Additional Registrational Clinical Trials, our conditional NDA for LP-168 may be revoked.
4. As confirmed by the FDA in July 2025, LP-168 initiated an FDA-regulated Phase III clinical trial in January 2026 without conducting Phase II clinical trial.
5. The Phase I clinical trials for LP-168 in the U.S. and China are designed as to enroll patients across various cancer types into separate, indication-specific cohorts. Based on the preliminary efficacy and safety data generated from each cohort, we will strategically advance promising indications into Phase II or Phase III clinical trials. Where applicable, our strategy is to leverage expedited regulatory pathways to seek conditional NDA approval based on Phase II clinical trial results. This pipeline chart reflects only the specific indications for which clinical trials are currently active and ongoing and it does not exhaustively list all potential indications covered by the broader trial design, as the clinical endpoints for certain cohorts have not yet been reached and the corresponding data analyses have not yet been finalized.
6. LP-168’s current NDA application under review is for its use as a monotherapy for the treatment of adult patients with relapsed or refractory MCL who have previously received at least two prior lines of systemic therapy, including a BTK inhibitor, thereby positioning it as a potential third-line treatment option for MCL.

BUSINESS

Our BeyondX Oral MedChem Platform

We have developed a medicinal chemistry platform to design orally bioavailable “Beyond Rule of 5” (bRo5) small molecules — a new chemical space beyond traditional drug design. This platform enables us to significantly accelerate the design and discovery of orally bioavailable bRo5 medicines which may possess novel biological mechanisms of action not achievable by conventional “Ro5” small molecule inhibitors, or can offer the potentials to target a broad spectrum of historically “undruggable” biological targets. Our BeyondX platform directly addresses this industry-wide challenge and successfully yield orally bioavailable bRo5 drug candidates with three competitive advantages:

- **Potency and Efficacy.** Our bRo5 drug candidates are optimized to fill entire binding pockets and form multiple interactions (covalent bonds, hydrogen bonds, van der Waals forces, among others), driving strong target binding and therapeutic effects. As of the Latest Practicable Date, our BeyondX platform supports the development of molecules with a molecular weight of up to 1,250 g/mol and a binding pocket area of up to 1,000 Å². We are actively conducting R&D activities to further expand these technical boundaries and broaden the platform’s applicability.
- **Selectivity and Safety.** The larger bRo5 molecular structures provide a steric hindrance that can minimize off-target protein interactions. This improved selectivity for the intended target translates into a more encouraging safety profile.
- **Pharmacokinetics.** Our bRo5 compounds are engineered to evade rapid metabolism by liver enzymes, thereby overcoming the typical high-clearance issues of bRo5 drugs. This results in low clearance and sustained drug exposure; for instance, LP-168 exhibits high drug exposure and a encouraging PK profile in humans.



As illustrated in the image above, Beyond-Rule-of-Five (bRo5) small molecules have much higher molecular weight than the traditional “Ro5” small molecules. The dotted lines represent areas of our active R&D focus that extend beyond the parameters of our current drug candidate portfolio.

Source: Company information

COMPETITIVE STRENGTHS

Our Core Product LP-168: a “covalent & non-covalent” dual-mechanism BTK inhibitor under NDA stage with promising efficacy, safety, and anti-resistance profile overcoming existing BTKi’s limitations and resistance

LP-168 is an NDA stage BTK inhibitor, which innovatively designed to address drug resistance in malignant B cells by combining both covalent & non-covalent binding mechanisms in one single small-molecule compound. It can bind to the BTK in two ways — forming a covalent bond at a C481 residue on the wild-type BTK protein, and binding non-covalently to BTK even if that C481 residue is mutated. This unique dual-action design allows LP-168 to target both wild-type

BUSINESS

BTK and mutant BTK, and this innovative approach overcomes the resistance limitations inherent in traditional three prior generations of BTK inhibitors (such as ibrutinib, acalabrutinib, zanubrutinib, pirtobrutinib) that rely on single-mechanism covalent or non-covalent binding alone.

We believe LP-168 has the following advantages compared to other approved and clinical-stage BTK inhibitors.

- ***Unique dual Covalent & Non-covalent Design with encouraging PK profile.*** LP-168 is a BTK inhibitor to incorporate both covalent & non-covalent binding mechanisms. This dual design enables LP-168 to achieve sustained and durable BTK inhibition, even in the presence of resistance-associated mutations such as C481S that limit the efficacy of earlier covalent inhibitors. By combining the strong, irreversible target engagement of covalent binding with the flexibility of non-covalent interactions, LP-168 delivers higher PK exposure, a longer half-life, and sustained bioavailability compared to earlier generation covalent BTK inhibitors.
- ***Significant Potential in the DLBCL Treatment Market.*** DLBCL is the most common non-Hodgkin lymphoma (“NHL”) subtype, representing approximately 40% of the total cases and is widely considered the most challenging due to its high heterogeneity, complex molecular mechanisms, and treatment resistance. As of the Latest Practicable Date, no BTK inhibitor monotherapy or combination had been approved for DLBCL.

In Phase I clinical trials, LP-168 achieved an overall response rate (ORR) of 72.2% and a complete response (CR) rate of 33.3% at ≥ 200 mg QD in patients with R/R non-GCB DLBCL. The survival benefit is equally compelling with median PFS of 7.1 months (median follow-up: 8.1 months) and 64.2% of patients achieving durable response of 12 months. All primary endpoints of the Phase I clinical trial in patients with R/R B-cell lymphoma in China for R/R non-GCB DLBCL cohort were reached in April 2024. Therefore, we considered that we had completed the Phase I clinical trial with respect to the R/R non-GCB DLBCL cohort. Based on the outstanding efficacy data, LP-168 was granted Breakthrough Therapy Designation in China for R/R non-GCB DLBCL. Building on Phase I data and through strategic engagement with CDE, we successfully refined the Phase II registrational trial design for R/R non-GCB DLBCL and initiated such registrational clinical trial in China in November 2025.

- ***Efficacy in Oncology.*** LP-168 has demonstrated outstanding clinical efficacy in the oncology field, highlighting its differentiated therapeutic value.
- ***MCL.*** LP-168 has shown clinical benefits in treating relapsed/refractory mantle cell lymphoma (R/R MCL), especially in patients who have progressed upon previous BTK inhibitor treatment. LP-168 achieved an ORR of 63.9%. This significantly exceeded pirtobrutinib’s roughly 50% ORR based on publicly available information. Importantly, LP-168’s advantages were preserved even in hard-to-treat cases. Patients on LP-168 therapy had a median progression-free survival (PFS) of 7.4 months.
- ***CLL/SLL.*** In the field of R/R CLL/SLL, LP-168 has demonstrated encouraging efficacy compared to the third-generation reversible BTK inhibitor pirtobrutinib among patients who have failed prior BTK inhibitor therapy. The ORR in the overall LP-168 all-dose cohort was 62.5%. Among patients receiving the recommended dose of 200 mg once daily or higher, the ORR reached 78.3%. Regarding survival data, as of a median follow-up of 30.3 months, LP-168’s median progression-free survival remains immature and is estimated at 28.1 months. This suggests a substantial long-term survival benefit with LP-168. Notably, LP-168 was tested in a challenging patient group — those who had received four previous therapies. Additionally, 45% of LP-168 patients had tried two or more BTK inhibitors. Furthermore, in patients carrying the BTK T474 mutation (which confers resistance to first-, second-, and third-generation BTK inhibitors), LP-168 achieved an ORR of 80% and a disease control rate (DCR) of 100%. This mutation is also one of the main reasons for resistance to pirtobrutinib, highlighting LP-168’s potential to overcome that challenge.

BUSINESS

- **MZL.** In BTK inhibitor-naïve R/R MZL patients, LP-168 achieved notably high response rates with an ORR of 75.8% and CR of 24.2%. LP-168 also delivers durable disease control with 86.2% of patients achieving 12 month DOR at a median follow-up of 16.2 months.
- **PCNSL.** In the Phase I clinical trial, we have also enrolled three R/R PCNSL subjects. In these three subjects, LP-168 achieved a 100% ORR with one complete response unconfirmed and two partial responses. CNS target lesions showed sum of products of diameters reductions ranging from 64.1% to 83.8%. This efficacy profile is supported by the CNS penetration ability of LP-168 and its ultra potent inhibitory activity against BTK.
- **Promising Safety Profile Enabling Long-Term Use.** LP-168 directly addresses the key safety shortcomings of existing BTK inhibitors. LP-168 demonstrates a TRAE-related discontinuation rate of just 0.7%, significantly lower than ibrutinib (~26%), acalabrutinib (13%-22%) and zanubrutinib (2%-13%), and pirtobrutinib (9%). In addition, LP-168 exhibits low rates of adverse events compared to approved BTK inhibitors. ≥Grade 3 infections occur in only 8.3% of patients, significantly lower than ibrutinib (21.0%), acalabrutinib (19.0%), zanubrutinib (24.0%), and pirtobrutinib (24.0%).
- **Significant potential in autoimmunity.** LP-168 has strategically expanded into autoimmune indications, positioning the asset beyond oncology to capture significant value in the rapidly growing autoimmune therapeutics market. LP-168 has initiated clinical studies in chronic spontaneous urticaria with plans to expand into major autoimmune indications including ITP, pMN, MS, and gMG. In Phase I clinical trial in healthy subjects, LP-168 demonstrated an overall safety profile at 12.5mg-75mg QD with no grade 2 or higher TRAEs observed, while achieving near-complete BTK target occupancy (~100%) at 2 hours after a single 12.5 mg dose that sustained for over 24 hours.

LP-168, demonstrates favorable PK characteristics compared to prior-generation BTK inhibitors. LP-168's PK exposure in humans is approximately 80 times greater than that of ibrutinib. It also achieves about 50 times the exposure of acalabrutinib, 35 times that of zanubrutinib, and 10 times that of orelabrutinib. In addition, LP-168 has a longer half-life, enabling convenient once-daily dosing and thereby improving patient compliance.

LP-168 addresses a broad market encompassing blood cancers and autoimmune diseases, with patients requiring long-term treatment. LP-168's differentiated profile positions it to capture significant market share across both established oncology indications and emerging autoimmune applications. The asset's ability to address resistance mechanisms and deliver sustained responses supports premium pricing potential and long-term revenue generation in these chronic disease settings where patients require years of continuous therapy.

Bcl-2 candidate LP-108 and first-in-industry Bcl-2/Bcl-xL candidate LP-118 achieving delicate balance between anti-tumor and on-target platelet toxicity

To augment our efforts to address hematological malignancies, we have developed LP-108, a selective Bcl-2 inhibitor, as well as LP-118, the industry's only oral dual inhibitor targeting both Bcl-2 and Bcl-xL that achieves a delicate balance between anti-tumor activity and on-target platelet toxicity.

LP-108. LP-108 is a selective Bcl-2 inhibitor that, when combined with LP-168, is positioned to become the optimal treatment regimen for CLL/SLL. LP-108 demonstrates differentiations over existing therapies through its unique dose ramp-up schedule, optimized pharmacokinetic properties, and encouraging clinical efficacy across multiple studies. This differentiated profile offers R/R CLL/SLL patients a more effective and safer treatment option with the potential to establish new standards of care in this therapeutic area.

BUSINESS

- **Rapid dose escalation advantage.** LP-108 demonstrates an improvement in dose escalation compared to traditional Bcl-2 inhibitors. While conventional Bcl-2 inhibitors such as venetoclax require a lengthy 5-week dose ramp-up period (gradually increasing from 20mg to 400mg) to mitigate tumor lysis syndrome (“TLS”) risk, LP-108 achieves the recommended therapeutic dose (400mg QD) safely within just five days through an optimized daily dose escalation protocol. This significant reduction substantially enhances dosing convenience and reduces early-stage risks associated with prolonged subtherapeutic dosing.
- **Encouraging clinical efficacy.** Based on its preliminary clinical trial results, LP-108 demonstrates broad and durable efficacy in R/R CLL/SLL patients. Current study results show that for patients who have received prior BTK inhibitor therapy (N=20), LP-108 achieved an ORR 70%, cCR/CRi rate of 20%, and DCR of 100%. The median DOR and PFS have not been reached. Estimated 18 month PFS rate and DOR rate are 74.8% and 74.3% respectively, indicating significant long-term disease control potential.
- **Safety profile.** LP-108 demonstrated a safety profile with no permanent discontinuation due to TRAEs, significantly lower than the reported rates of 9% for venetoclax and 4.7% for sonrotoclax. The severe AE rate was 21.2%, substantially lower than venetoclax’s 52%.
- **Combination therapy strategy.** We are exploring opportunities for the combination therapy of LP-108 with LP-168, which we have obtained an IND approval from the NMPA for mature B cell malignancies. According to CIC, we are one of the first companies in China obtaining the IND for a combination therapy of BTK inhibitor and Bcl-2 inhibitor. Preclinical data indicate that the doublet can achieve deep cancer cell clearance (high MRD-negative rates), positioning it to potentially become the world’s “infusion-free, chemotherapy-free” treatment regimen for CLL/SLL. We currently expect to initiate Phase I/II clinical trial for the combination therapy with LP-108 and LP-168 in the second quarter of 2026 in China. Additionally, we have obtained FDA approval for a Phase II study of LP-108 in combination of LP-168 in R/R CLL/SLL and the study is planned to be initiated in the second half of 2026 in the United States.

LP-118. We have developed LP-118, an oral dual-target inhibitor of Bcl-2 and Bcl-xL that uniquely achieves delicate balance between anti-tumor activity and on-target platelet toxicity. As of the Latest Practicable Date, we had completed the Phase I clinical study for LP-118 in patients with advanced tumors in China. In addition, we are also conducting Phase Ia/Ib clinical trials for LP-118 in the United States, and we expect we will complete the dose escalation stage of its Phase Ia/Ib clinical trial for patients with R/R hematological malignancies in the United States by the third quarter of 2026.

- **Rationale Design Achieves a Delicate Balance Between Anti-tumor Activity and On-target Toxicity.** We have taken an innovative approach by proposing a key hypothesis in our drug design: the inhibitory activity against Bcl-xL must be maintained within a moderate range. This way, we can fully harness Bcl-xL’s anti-cancer effects while keeping its on-target platelet toxicity under control. As a result, we achieve a delicate balance between anti-cancer activity and on-target platelet toxicity. Preclinical studies have validated this approach with LP-118.
- **Efficacy in SCLC.** Based on preliminary clinical trial results from its Phase I clinical trial in China, LP-118 has demonstrated therapeutic potential in SCLC, a highly aggressive neuroendocrine tumor with rapid progression and limited treatment options. LP-118 achieved an ORR of 13.9% and DCR of 69.4%. The drug exhibited both rapid onset and durable disease control, with five patients achieving partial response after just one treatment cycle and two patients maintaining stable disease for over 12 cycles. Notably, 90.5% of enrolled patients had previously received immunotherapy with a median of two prior treatment lines, representing a heavily pretreated population with limited therapeutic options, yet LP-118 still achieved nearly 70% DCR, demonstrating significant clinical value for patients who have failed multiple prior therapies.

BUSINESS

- ***Broad efficacy across multiple NHL subtypes.*** LP-118 has shown impressive activity across various subtypes of NHL, including challenging cases that are typically resistant to existing treatments. In patients with DLBCL (including transformed cases such as the difficult-to-treat Richter’s transformation), LP-118 achieved an ORR of 75%, with one patient achieving complete responses and two achieving partial responses out of four treated patients. In MCL, one patient who had previously failed BTK inhibitor treatment achieved complete response. Responses were observed across other lymphoma subtypes, including partial responses in heavily pre-treated chronic lymphocytic leukemia and cutaneous T-cell lymphoma patients, and one marginal zone lymphoma patient maintaining stable disease for over 24 months. Notably, LP-118 exhibited demonstrated anti-tumor activity in heavily pretreated patients who had failed multiple prior lines of therapy (median prior treatment lines: 2, range: 1-6), addressing medical needs in relapsed/refractory settings where treatment options remain severely limited.
- ***Broad-Spectrum Anti-cancer Activity.*** Due to the important role of Bcl-2 and Bcl-xL in cancer cell survival, LP-118 is a potentially broad-spectrum anti-cancer drug addressing multiple types of cancer.
 - It has demonstrated efficacy in both solid tumors and blood cancers. For example, LP-118 has shown activity against SCLC and various blood malignancies, including leukemias like T-cell acute lymphoblastic leukemia (“**T-ALL**”) and CLL, as well as several forms of lymphoma such as DLBCL, MCL, and cutaneous T-cell lymphoma (CTCL).
 - LP-118 also offers hope for patients who have developed resistance to existing treatments. The drug can target mutated forms of the Bcl-2 protein (such as the G101V mutation), providing a new treatment option for patients with CLL or acute myeloid leukemia (“**AML**”) who are no longer responding to venetoclax (a standard Bcl-2 inhibitor therapy). This ability to overcome certain drug resistances could make LP-118 an important alternative for difficult-to-treat patient populations.
 - LP-118 has significant potential in combination therapy. Preclinical results suggest that using LP-118 alongside other treatments could enhance its effectiveness. It may be combined with targeted therapies like BTK inhibitors, immunotherapies such as anti-CD20 monoclonal antibodies, or even traditional chemotherapy to improve patient outcomes. Several clinical trials are currently being planned to evaluate LP-118 in these combination therapy regimens, reflecting the broad interest in maximizing the drug’s therapeutic impact.

Self-developed BeyondX Oral MedChem Platform to develop bRo5 oral small molecule therapeutics — a new chemical space beyond traditional drug design

We are a pharmaceutical company in targeted bRo5 oral small-molecule therapeutics, having independently developed our BeyondX Oral MedChem Platform. We focus on the rational drug design, discovery, preclinical and clinical development, manufacturing, and commercialization of bRo5 oral small-molecule therapeutics to address the unmet needs of cancer and autoimmune patients worldwide. Our BeyondX Oral MedChem Platform primarily consisted of three sub-platform, namely covalent & non-covalent sub-platform, protein-protein interaction sub-platform and PROTAC sub-platform.

Our BeyondX Oral MedChem Platform directly addresses this industry-wide challenge through specialized design innovations, yielding drug candidates with three competitive advantages, namely (i) our bRo5 drug candidates are optimized to fill entire binding pockets and form multiple interactions (covalent bonds, hydrogen bonds, van der Waals forces, among others), driving strong target binding and therapeutic effects; (ii) the larger bRo5 molecular structures provide a steric hindrance that can minimize off-target protein interaction to achieve improved target specificity; and (iii) bRo5 compounds are engineered to evade rapid metabolism by liver enzymes, thereby overcoming the typical high-clearance issues of bRo5 drugs.

BUSINESS

We are advancing multiple oral bRo5 drug candidates, including next-generation covalent/non-covalent dual mechanism inhibitors, protein-protein interaction disruptors, and PROTACs, which position us for accelerated and sustained growth in innovative small-molecule therapies.

Clinical execution efficiency, commercial readiness and proven business development record supported by strong execution capabilities with strategic market positioning

Clinical Execution Efficiency

We have a highly specialized clinical development team and have implemented a clear global clinical strategy. We have advanced three clinical-stage assets covering over ten indications with high commercial potential, across hematologic malignancies, solid tumors, and autoimmune diseases, with over 500 subjects enrolled as of the Latest Practicable Date. We have demonstrated clinical execution efficiency with our NDA-stage Core Product LP-168, completing the journey from first patient dosing to NDA submission for R/R MCL in less than four years, significantly shorter than industry average according to CIC. Building on Phase I data and through strategic engagement with CDE, we initiated the Phase II registrational trial design for R/R non-GCB DLBCL for LP-168 in November 2025. Notably, we are one of the few companies that have experiences in advancing clinical trials in both China and the United States. These achievements underscore our proven capabilities in clinical trial design, rapid execution, and effective regulatory engagement, positioning us to accelerate development milestones across our pipeline.

Commercialization Readiness

We have adopted a dual-track commercialization strategy, combining in-house sales and marketing capabilities with strategic partnerships. Although the NDA approval is expected to be a conditional NDA approval, it will not restrict our ability to market and sell the product in line with its approved indication, namely, the treatment of adult patients with R/R MCL who have previously received at least two prior lines of systemic therapy, including a BTK inhibitor. We are required to complete an Phase III head-to-head clinical trial, which serves as a post-marketing commitment that will not impede our ongoing commercialization activities. In anticipation of LP-168’s near-term commercialization in China, we are actively building a specialized sales team of 80 personnels by the end of 2026, across marketing, sales, and medical affairs functions. We believe an 80-person team can provide the geographic coverage and physician penetration necessary to establish durable market share across our target regions. Our sales representatives are strategically deployed across Northern, Southern and Eastern China, enabling us to access the key hospitals and patient populations for LP-168’s approved indication. Each regional team will be based in close proximity to the major Class III hospitals, which would facilitate frequent in-person engagement with physicians. This localized presence will also allow our representatives to attend regional academic conferences, hospital-based educational forums and other professional events on a regular basis, ensuring that they remain integrated within the local medical community.

As of the Latest Practicable Date, we had appointed our national sales head and market director, each of who had over 18 years of experience in pharmaceutical company, featuring strong backgrounds in central marketing and frontline sales, alongside a demonstrated history of assembling high-performing commercial teams and launching hematology therapies. Our national sales head and market director operate in a complementary manner: the national sales head focuses on securing and maintaining institutional access, while the market director shapes the broader strategic environment that enables successful product adoption. In particular, our national sales head is primarily responsible for establishing and executing the hospital access framework necessary to bring LP-168 into target institutions, including educating hospital-level committees, ensuring compliance with applicable public policy requirements, as well as building strategic relationships with senior hospital leadership, coordinating cross-departmental resources to support access initiatives and overseeing access project management and data analytics. Our market director is responsible for defining our product strategy and brand positioning, building physician networks and academic platforms, as well as, developing and managing our marketing promotion framework.

BUSINESS

In addition to our strategic sales teams, we also plan to focus on on China’s top 500 Class III hospitals, particularly China’s top 150 oncology hospitals. This focus is commercially justified and aligns with the strategic deployment of our sales team, whom are primarily located in the cities where China’s top 500 Class III hospitals are concentrated, for the following reasons: (i) the top 500 Class III hospitals account for a major portion of the NHL treatment in China, representing the most concentrated source of eligible patients for LP-168; and (ii) these institutions serve as academic leaders and clinical bellwethers, therefore establishing LP-168’s professional brand within these hospitals during the early launch phase is critical to building broader market acceptance.

We plan to establish a nationwide distribution network to enhance our product’s market access in China. We will adopt a flexible pricing strategy, with a premium pricing relative to existing BTK inhibitors considering the novel covalent and non-covalent mechanism of LP-168. Further, we plan to explore opportunities to include LP-168 in the NRDL, which we believe will further enhance our product’s market access. We have already formulated a detailed plan to include LP-168 in the NRDL in the first NRDL negotiation following its approval, and have already started to work with KOLs to prepare for NRDL negotiation. We expect this focused approach to enable rapid hospital penetration and precise patient targeting upon market entry.

Proven Business Development Record

While building our in-house sales and marketing capabilities, we are actively pursuing strategic business development opportunities with global pharmaceutical companies. In August 2024, we secured a strategic partnership with Hansoh Pharma for LP-168, granting them exclusive rights to research, develop, register, manufacture and commercialize for all non-oncology indications in Chinese mainland, Hong Kong, Macau and Taiwan. For details, see “— Licensing Agreement — License Agreement with Hansoh Pharma for LP-168.” Looking ahead, we will focus on out-licensing or co-development opportunities for international markets, leveraging partners’ established clinical infrastructure and commercial networks to accelerate global expansion. These partnerships will generate non-dilutive capital to fund our continued pipeline development while maximizing the worldwide potential of our assets.

Proven world-class management team with pharmaceutical experts and reputable entrepreneurs

Our senior management team comprises seasoned professionals with extensive international experience across the pharmaceutical value chain, from novel drug discovery through clinical development, regulatory affairs, and commercialization. With a proven track record of advancing multiple product candidates from discovery to market approval and launching breakthrough therapies globally, our leadership has been instrumental in defining our strategic vision and executing on our ambitious development programs. Their deep industry relationships and operational expertise enable us to navigate complex regulatory pathways, forge strategic partnerships, and capitalize on emerging market opportunities. For details, see “Directors and Senior Management — Board of Directors.”

Our integrated R&D organization comprises 79 professionals across pre-clinical and clinical development as of the Latest Practicable Date, with over 40% holding master’s or higher degrees from internationally renowned institutions. The pre-clinical R&D team, led by Dr. Chen, our executive Director and CSO, operates with particular expertise in navigating the complex challenges of bRo5 oral small molecules. The clinical development team, led by Dr. Tan, our chairman, executive Director, CEO and CMO and composed of former core members from Novartis and Betta Pharmaceuticals, has demonstrated execution capabilities by independently managing over 10 global registration clinical studies and achieving the remarkable milestone of advancing LP-168 for R/R MCL from first patient’s enrollment to NDA submission in less than four years — significantly outpacing industry benchmarks.

Since our inception, we have secured continuous support from leading international and domestic biomedical venture capital funds. For details, see “History, Reorganization and Corporate Structure — Pre-[REDACTED] Investments.”

BUSINESS

BUSINESS STRATEGY

Drive LP-168 towards commercialization in China as first-line therapy for oncology and autoimmune diseases while progressing clinical trials and registration activities in global markets

LP-168, our Core Product, is our most advanced drug candidate. In May 2025, we submitted the NDA to the NMPA for the treatment of R/R MCL, which was accepted by the NMPA. We expect that LP-168 will receive the conditional NDA approval for R/R MCL by June 2026. As stated in the SCL, also need to mention: the scope of such permitted sales (e.g. geographical coverage, eligible patient population and lines of treatment. We do not expect such approval to impose any specific restrictions regarding geographical coverage, eligible patient populations, or lines of treatment. We plan to rapidly advance the commercialization of LP-168 for R/R MCL. We are also advancing clinical trials for LP-168 in other oncology indications. For example, LP-168 was granted Breakthrough Therapy Designation for the treatment of R/R non-GCB DLBCL in May 2024. We initiated the registrational clinical trial for treatment in R/R non-GCB DLBCL in November 2025 and plan to submit the conditional NDA application for LP-168 for the treatment of R/R non-GCB DLBCL in 2027. We are also advancing the development of LP-168 in R/R MCL (BTK naïve) patients. In January 2026, we initiated a head-to-head Additional Registrational Clinical Trial in China evaluating LP-168 versus approved BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib, or orelabrutinib) for R/R MCL, anticipating enrollment of approximately 394 subjects.

For LP-168, we are currently advancing clinical development in the United States for the treatment of CLL/SLL, leveraging its differentiated mechanism of action and improved selectivity profile. To maximize the global commercial value of this innovative asset, we are actively exploring strategic business development opportunities that could accelerate market access and broaden geographic reach, while maintaining our commitment to advancing LP-168 through critical development milestones. We are also developing LP-168 for the treatment of R/R CLL/SLL in the United States with a phase III head-to-head trial of LP-168 against pirtobrutinib in R/R CLL/SLL patients underway to support its global registration. In addition, the first patient was enrolled in May 2026.

Our development strategy also encompasses multiple non-oncology indications with substantial market potential, particularly autoimmune diseases. Through strategic collaboration with Hansoh Pharma, we are accelerating the clinical development timeline across multiple indications. Through our collaborator Hansoh Pharma, a Phase I/II clinical trial for chronic spontaneous urticaria (CSU) has been initiated in China in 2025, with plans to further expand into additional autoimmune indications. Furthermore, this collaboration approach not only expands LP-168’s addressable patient population across multiple autoimmune conditions but also leverages Hansoh Pharma’s established capabilities to accelerate development timelines and enhance commercial potential in key markets. We are also exploring opportunities in overseas markets in the field of autoimmune diseases for LP-168 and will seek IND filing and advance clinical trials in the future.

We plan to apply for approximately [REDACTED]% of the [REDACTED] from the [REDACTED] to the continuous research and development activities of LP-168. For Details, see “Future Plans and [REDACTED] — [REDACTED].”

Advance the clinical development and commercialization of LP-108 and LP-118

- **LP-108.** We believe LP-108 has significant potential in combination therapy with LP-168, for which we have obtained an IND from the NMPA. We plan to initiate its Phase I clinical trial by June 2026 in China. In addition, we obtained the FDA approval for the Phase I/II trial for LP-108 in combination with LP-168 in March 2026 and we expect to initiate patient enrollment in the second half of 2026. We also plan to initiate a Phase II clinical trial for LP-108 as monotherapy for the treatment of R/R CLL/SLL by June 2026. In addition, we are developing LP-168 and LP-108, a Bcl-2 inhibitor, as a combination therapy for mature B-cell

BUSINESS

neoplasms, having obtained IND approval from China’s NMPA, and believe this infusion-free, chemotherapy-free regimen has the potential to become a promising, front-line treatment across multiple B-cell malignancies.

- **LP-118.** We have received IND approvals for LP-118 from both the FDA and NMPA for several indications. For SCLC and R/R NHL, we have completed a Phase I dose escalation/dose expansion study in China and obtained preliminary efficacy data and optimal dosing range of LP-118 for SCLC. In the United States, we are progressing with dose escalation studies for R/R hematological cancers and we plan to complete it in 2026. We will also advance clinical trials with LP-118 for R/R T-ALL/LBL, from which we have already seen encouraging efficacy signal. We obtained IND approval from the FDA for LP-118 in February 2026 for a Phase I study of the Bcl-2/Bcl-XL inhibitor LP-118 in combination with ponatinib, dexamethasone and blinatumomab in adults with newly diagnosed Philadelphia chromosome/BCR::ABL1-positive acute lymphoblastic leukemia (Ph+ ALL), and the study is planned to be initiated in the second half of 2026.

We plan to apply for approximately [REDACTED]% of the [REDACTED] from the [REDACTED] to the continuous R&D of LP-118 and LP-108 in China. For Details, see “Future Plans and [REDACTED] — [REDACTED].”

Continue to pursue innovation supported by our BeyondX Oral MedChem Platform in oncology and autoimmune diseases

Leveraging our BeyondX Oral MedChem Platform, we will continue to deepen our expertise in oncology and autoimmune diseases. Through this platform, we aim to consistently deliver novel therapeutics that can further strengthen our differentiated competitive position. We will continue to cultivate our covalent & non-covalent design, PPI and PROTAC sub-platform, and explore opportunities in other targets, including BTK PROTAC, MDM2 PROTAC and KRAS PROTAC.

With a focus in oncology and autoimmune diseases, we believe our BeyondX Oral MedChem Platform represent a significant technological moat in addressing traditionally “undruggable” targets. By pushing the boundaries of oral bioavailability for complex molecules that exceed conventional drug-like parameters, we are uniquely positioned to develop therapies that combine encouraging efficacy with patient-friendly oral administration, creating substantial value for patients and shareholders alike.

We plan to apply for approximately [REDACTED]% of the [REDACTED] from the [REDACTED] to continue to develop our BeyondX Oral MedChem Platform. For Details, see “Future Plans and [REDACTED] — [REDACTED].”

Pursue strategic business development opportunities to accelerate commercialization

We are actively executing a strategic business development approach that leverages partnerships to maximize the commercial potential of our innovative pipeline. Our collaboration with Hansoh Pharma not only validates the clinical and commercial value of our assets but also provides significant non-dilutive funding, accelerates market access, and enables us to focus resources on advancing our broader pipeline while ensuring optimal commercialization through a partner with proven execution capabilities.

Building on the success of the collaboration with Hansoh Pharma, we continue to explore innovative partnership models overseas across different countries and therapeutic areas, including regional licensing agreements, co-development partnerships, and commercial alliances. Our business development strategy is designed to be flexible and value-maximizing, allowing us to retain rights in key markets where we plan to build internal capabilities while partnering in regions where established players can drive effective market penetration.

We plan to apply for approximately [REDACTED]% of the [REDACTED] from the [REDACTED] to support the commercialization activities for LP-168 in China. For Details, see “Future Plans and [REDACTED] — [REDACTED].”

BUSINESS

Retain and attract R&D and management talents and enhance organizational capabilities

We recognize that our success fundamentally depends on the caliber of our scientific and management teams, making talent acquisition and retention a strategic priority. Our comprehensive approach focuses on recruiting R&D talents and experienced leaders from leading pharmaceutical companies and academic institutions globally, while nurturing internal talent through systematic professional development programs.

Our organizational capability building extends beyond individual talent to creating an integrated ecosystem that fosters innovation and operational excellence. We have implemented structured training programs covering technical skills, leadership development, and cross-functional collaboration.

OUR DRUG PORTFOLIO

Core Product LP-168 — “covalent & non-covalent” dual-mechanism BTK inhibitor under NDA stage

Overview

LP-168, is a “covalent & non-covalent” dual-mechanism BTK inhibitor under NDA stage. LP-168 is innovatively designed to address drug resistance in B-cell cancer cells by combining both covalent & non-covalent binding mechanisms in one single small-molecule compound. It can bind to the BTK enzyme in two ways — forming a covalent bond at a C481 residue on the wild-type BTK protein, and binding non-covalently to BTK even if that C481 residue site is mutated. This unique dual-action design allows LP-168 to target both wild-type BTK and mutant BTK, and this innovative approach overcomes the resistance limitations inherent in traditional first- to three-generation BTK inhibitors (such as ibrutinib, acalabrutinib, zanubrutinib, pirtobrutinib) that rely on single-mechanism covalent or non-covalent binding alone. The drug candidate demonstrates high potency, selectivity (over 700-fold selectivity for BTK versus other off-target kinases), and pharmacokinetics supporting once-daily oral dosing.

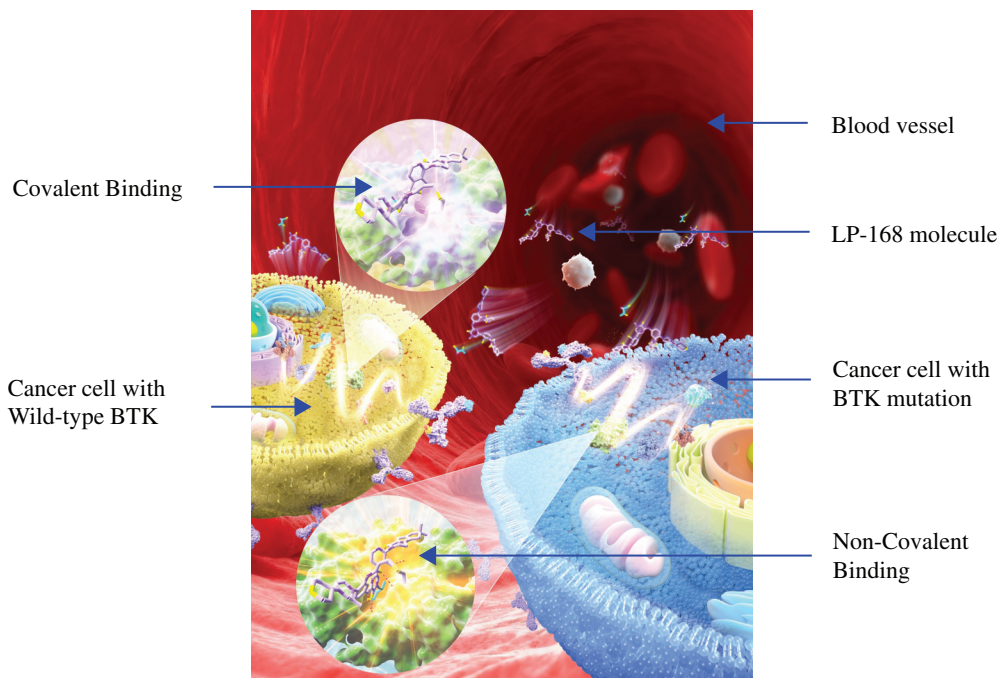
As of the Latest Practicable Date, our most advanced LP-168 program was its use in R/R MCL, for which we had completed its registrational clinical trial and have submitted its NDA application to the NMPA in the first half of 2025. We currently expect to obtain the NDA approval by June 2026. In August 2024, we entered into a licensing agreement with Hansoh Pharma (03692.HK), pursuant to which we agreed to grant Hansoh Pharma an exclusive license to research, develop, register, manufacture and commercialize LP-168 for non-oncology indications in Chinese Mainland, Hong Kong, Macau and Taiwan. In November 2025, we further entered into a supplementary agreement with Hansoh Pharma for us to serve as the sponsor for a Phase II clinical trial in the MS indication within the aforementioned territories. For details, see “— License Agreement.”

Drug Design and Mechanism of Action

BTK is a critical signaling node in B-cell, Toll-like, and Fc receptors. By preventing the phosphorylation of downstream effectors (e.g., PLC• γ 2) and NF- κ B activation, BTK inhibitors effectively halt B-cell proliferation and inflammation. The development of these inhibitors spans three generations. First-generation covalent inhibitors (e.g., ibrutinib) bind irreversibly to the C481 residue but are limited by off-target toxicities and C481 mutation-driven resistance. Second-generation covalent inhibitors (e.g., acalabrutinib, zanubrutinib) improved selectivity and tolerability but remain susceptible to C481 mutations. To overcome this, third-generation non-covalent inhibitors (e.g., pirtobrutinib, nemtabrutinib) were developed to bind reversibly, independent of C481, thereby retaining therapeutic activity against both wild-type and C481-mutant BTK.

BUSINESS

LP-168 is a highly selective BTK inhibitor designed to overcome resistance to prior BTK inhibitors. It binds tightly in the ATP-binding site of BTK, forming a covalent bond with cysteine 481 while also establishing key hydrogen bonds for stability. Importantly, LP-168 retains strong inhibitory activity against both wild-type BTK and clinically relevant resistant mutations such as C481S, T474I, and L528W. This leads to potent and durable suppression of B-cell receptor (BCR) signaling, blocking downstream activation of PLC γ 2, ERK, and AKT, and reducing NF κ B-driven survival genes and cytokine production.



Mechanism of Action of LP-168 — Illustration of the blood microenvironment, including blood vessels, red blood cells, white blood cells, cancer cells (with wild-type BTK shown in yellow and mutant BTK shown in blue), and the LP-168 molecule. In cancer cells with wild-type BTK (yellow), LP-168 covalently binds to BTK (binding illustrated by a glow effect). In BTK-mutant cancer cells (blue), LP-168 binds to BTK through a non-covalent mechanism (glow indicates binding). As a result, LP-168 can target cancer cells regardless of BTK mutation status through either covalent or non-covalent binding, potentially leading to improved anti-tumor efficacy.

Market Opportunity and Competition

As of the Latest Practicable Date, there were six approved or NDA filed BTK inhibitors, including LP-168. Although there are also four BTK inhibitors under clinical trial worldwide, all of them are second or third generations of BTK inhibitors, which adopts either covalent or non-covalent binding model.

Major globally approved or NDA filed BTK inhibitors, as of latest practicable date

Brand name	INN	Binding mode	Company	First approval date/region	Indications	Route of administration	NRDL
IMBRUVICA® 億珂®	Ibrutinib	Covalent	Janssen	2013/11 FDA 2018/01 NMPA	CLL/SLL $\pm$ 17p deletion, MCL, WM, cGVHD	Oral	Category B
CALQUENCE® 康可期®	Acalabrutinib	Covalent	AstraZeneca	2017/10 FDA 2023/03 NMPA	CLL/SLL, MCL	Oral	Category B
BRUKINSA® 百悦澤®	Zanubrutinib	Covalent	BeiGene	2019/11 FDA 2020/06 NMPA	CLL/SLL, MCL, WM, FL, MZL	Oral	Category B
宜諾凱®	Orelabrutinib	Covalent	InnoCare	2020/12 NMPA	CLL/SLL, MZL, MCL	Oral	Category B
JAYPIRCA® 捷帕力®	Pirtobrutinib	Non-covalent	Eli Lilly	2023/01 FDA 2024/10 NMPA	CLL/SLL, MCL	Oral	Not included
LP-168	Rocbrutinib	Covalent + Non-covalent (BIC)	Lupeng	2025/05 NDA filed with NMPA	MCL ¹ , DLBCL, MZL, CLL/SLL, and autoimmune diseases	Oral	N/A

Sources: CIC Report, NMPA, FDA.

BUSINESS

BTK inhibitors are used to treat a range of B-cell — driven diseases, most notably hematologic malignancies such as CLL/SLL, MCL, MZL, FL, WM and PCNSL, where aberrant B-cell receptor signaling drives survival and proliferation. Beyond cancer, BTKi have also shown promise in autoimmune and inflammatory disorders, where dysregulated B-cell activity contributes to disease pathology. According to CIC, the global BTK inhibitor drug market was US\$14.0 billion in 2025 and is expected to steadily increase to US\$20.0 billion in 2030 and US\$26.3 billion in 2035, at CAGRs of 6.6% from 2026 to 2030 and 5.6% from 2031 to 2035.

Summary of Clinical Development

Oncology

We obtained the IND approval for LP-168 in January 2021 from the FDA and March 2021 from the NMPA. The IND approvals granted by the NMPA and the FDA do not restrict the initial clinical evaluation to a specific cancer cohort. Accordingly, we have initiated two Phase I clinical trials, comprising one trial in China (NCT04993690) and one trial in the U.S. (NCT04775745), each evaluating the drug candidate across different types of tumors in various patient cohorts. The data derived from these Phase I trials serve as the clinical and regulatory foundation for advancing into indication-specific Phase II and Phase III clinical trials. Based on the MCL and DLBCL cohort data from LP-168’s Phase I clinical trial in China, we had successfully advanced its 3L R/R MCL (post BTKi) indication into NDA review stage and 2L R/R MCL (BTK naive) indication into head-to-head Phase III clinical trial stage and 2L R/R non-GCB DLBCL into Phase II registrational trial stage. In addition, based on LP-168’s Phase I clinical trial in the United States, we have completed its Phase I clinical trial in CLL/SLL cohort. We initiated a Phase III clinical trial in 2L R/R CLL/SLL (post BTKi) in the United States in January 2026. As of the Latest Practicable Date, we had completed its Phase II registrational clinical in R/R MCL subjects and submitted its NDA application to the NMPA in May 2025, which was accepted by the NMPA in the same month.

Pursuant to the Technical Guidelines for the Applicability of Single-Arm Clinical Trial to Support NDA Applications for Oncology Drugs (單臂臨床試驗用於支持抗腫瘤藥上市申請的適用性技術指導原則) issued by the NMPA in March 2023 (the “**March 2023 Technical Guidelines**”), a single-arm clinical trial may be used to support an NDA for an oncology drug only under specific circumstances, primarily where the disease is serious or life-threatening and there is a significant unmet medical need, and where conducting a randomized controlled trial is not feasible or would be ethically inappropriate. Both MCL and DLBCL are serious and life-threatening malignancies, especially in the relapsed or refractory setting. In particular, the five-year survival rate is generally reported at approximately 30% and 65% in MCL and DLBCL, respectively. Patients with relapsed or refractory MCL and DLBCL who have failed prior lines of therapy typically have limited treatment options, poor prognosis, and short survival duration, making it ethically and practically challenging to conduct large randomized controlled trials against suboptimal or declining standards of care. Therefore, LP-168 is eligible for conditional approval under the March 2023 Technical Guidelines. For details, please see “Industry Overview — Global and China BTK Inhibitor Market — Indications and Treatment Pathways for BTK Inhibitors.” Pursuant to the March 2023 Technical Guidelines, conditional approval framework generally requires the sponsor to conduct post-approval confirmatory randomized trials to verify clinical benefit.

In this regard, we hold separate regulatory communication meetings with the CDE in relation to our R/R MCL and R/R non-GCB DLBCL programs. With respect to R/R MCL, we convened a communication meeting with the CDE in July 2023. Following the meeting, the CDE agreed that a single-arm study design, with ORR as the primary endpoint, would be acceptable for this indication. With respect to R/R non-GCB DLBCL, we held a communication meeting with the CDE in April 2025. The CDE agreed to a randomized controlled trial design, comparing LP-168 against investigator’s choice of BR or R2 regimens, with ORR as the primary endpoint. Following each meeting, the CDE issued written minutes concurring with our proposed study designs and confirming that the Phase II studies may serve as the basis for conditional approval applications, subject to an overall benefit-risk assessment of the final study results.

Upon completion of the MCL and DLBCL cohort data from LP-168’s Phase I clinical trial in China, (a) the RP2D was established based on an integrated assessment of safety, pharmacokinetics, and preliminary efficacy; (b) the safety profile of LP-168 was determined to be manageable and consistent with the known class effects of BTK inhibitors; and (c) clinically meaningful efficacy signals were observed in the R/R MCL and non-GCB DLBCL cohorts. For details, please see “— Summary of Clinical Trial Development — Phase I Clinical Trials — Trial Results — R/R/MCL.” Given the unmet medical need in each indication and the strength of the cohort-specific efficacy and safety data, the Phase I results enabled the advancement of LP-168 into Phase II registrational studies adopting the RP2D, with patient eligibility criteria and primary endpoints aligned to the populations and activity observed in Phase I.

BUSINESS

Phase I Clinical Trials

Phase I Clinical Trial in Patients with R/R B-cell Lymphoma in China (NCT04993690)

Trial design. This is an open-label, multi-center Phase I study evaluating oral LP-168 in patients with CLL/SLL and NHL who have failed or are intolerant to standard of care therapy. The trial was initiated in July 2021, and we have enrolled 200 subjects for this trial at 25 trial sites in China as of the Latest Practicable Date. The study is designed in two stages: a dose escalation phase and a dose expansion phase.

- **Dose Escalation Phase.** This phase is designed with four initial dose cohorts targeting daily doses of 100 mg, 150 mg, 200 mg, and 300 mg, respectively. LP-168 is administered orally once daily (QD) at approximately the same time each day (either fasting or postprandial). If the maximum tolerated dose (MTD) is not reached at the fourth dose cohort (300 mg), the PI and our Company (as the sponsor) will review the available data to determine whether to escalate to higher doses or explore alternative dosing schedules (such as 150 mg twice daily (BID)). Any such modifications will be subject to protocol amendments and ethics committee approval.
- **Dose Expansion Phase:** In this phase, we plan to explore multiple dosing regimens, including 100 mg QD, 150 mg QD, 200 mg QD, and 300 mg QD, with the potential for higher or alternative doses (e.g., 150 mg BID) if deemed necessary.

To comprehensively evaluate LP-168 across various indications and patient backgrounds, the dose expansion phase stratifies patients into eight distinct cohorts, namely (a) R/R MCL who have failed prior covalent BTK inhibitors (20-30 subjects); (b) R/R CLL/SLL who have failed prior covalent BTK inhibitors (5-15 subjects); (c) R/R MCL who are naive to, or intolerant of, prior covalent BTK inhibitors (30 subjects); (d) R/R CLL/SLL who are naive to, or intolerant of, prior covalent BTK inhibitors (15-30 subjects); (e) R/R PCNSL or SCNSL (1-20 subjects); (f) other types of R/R B-NHL (55-100 subjects); (g) treatment-naive CLL/SLL (20 subjects); and (h) treatment-naive WM/LPL (1-5 subjects).

The respective cohorts in the Phase I study will serve as the foundation for our subsequent clinical development strategy. Upon evaluating the safety, preliminary efficacy, and pharmacokinetic/pharmacodynamic data derived from each cohort, we will determine the recommended Phase II dose (RP2D) for the respective indication. Subsequently, taking into account the prevailing clinical treatment paradigms and the competitive landscape for each specific indication, we will design rational and targeted Phase II or Phase III clinical trials.

Trial Status. Based on the tumor types, the subjects enrolled were divided into several cohorts. All primary endpoints for the R/R MCL cohort in our Phase I clinical trial in China were achieved on August 26, 2022, upon which we considered the MCL cohort complete. All primary endpoints for the non-GCB DLBCL cohort in our Phase I clinical trial in China were achieved on April 11, 2024, upon which we considered the DLBCL cohort complete. Following completion of the Phase I cohort, we initiated a Phase II clinical trial under the umbrella IND we obtained in March 2021. Based on our communications with the CDE, it confirmed that the Phase II clinical trial of LP-168 in R/R MCL conducted in China may be used to support our NDA submission for this indication. In addition, based on our separate communications with the CDE, it confirmed that the DLBCL cohort data from our Phase I clinical trial of LP-168 in China are sufficient to support the initiation of a Phase II registrational clinical trial in patients with R/R non-GCB DLBCL who have previously received BTK inhibitor therapy.

Trial Results:

R/R MCL

As of May 31, 2023, LP-168 demonstrated clinical efficacy across dose cohorts in 31 evaluable R/R MCL patients, achieving an ORR of 77.4%, including 38.7% (12/31) achieved CR/CMR and 38.7% (12/31) achieved PR/PMR. In 17 evaluable R/R MCL patients with prior BTK inhibitor treatment, consistent efficacy was observed with an ORR of 70.6% including CR/CMR rate of 35.3%. These compelling response rates, with particularly high complete response rates, demonstrate LP-168's potent anti-tumor activity in R/R MCL patients, particularly in overcoming resistance from the treatment of previous generation BTK inhibitors.

BUSINESS

Efficacy Data for R/R MCL Subjects

	100mg (N = 8)	Dosage 150mg (N = 22)	200mg (N = 1)	All Subjects (N = 31)
Response n (%)				
CR/CMR	4 (50.0%)	8 (36.4%)	0	12 (38.7%)
PR/PMR	2 (25.0%)	9 (40.9%)	1 (100.0%)	12 (38.7%)
SD	0	1 (4.5%)	0	1 (3.2%)
PD	2 (25.0%)	4 (18.2%)	0	6 (19.4%)
ORR n (%)	6 (75.0%)	17 (77.3%)	1 (100.0%)	24 (77.4%)
DCR n (%)	6 (75.0%)	18 (81.8%)	1 (100.0%)	25 (80.6%)

- As of June 15, 2025, being the latest cut-off date of this clinical trial, 28 BTKi-naïve R/R MCL patients were evaluable for efficacy. The overall response rate (ORR) was 89.3%, with a complete response (CR) rate of 57.1%. At median follow-up of 21.2 (range: 0.9-43.1) months, progression-free survival (PFS) is not matured yet. The estimated median PFS was 43.1 months, with 18-month PFS rate of 74.3%. Common treatment-related AEs are mostly Grade 1. No atrial fibrillation, Grade 3 hypertension or hemorrhage occurred. Dose interruption due to TRAEs occurred in 6 (21.4%) patients, but only 1 patient underwent dose reduction. No drug discontinuation or death due to TRAEs has occurred. Consistent with previously reported data above, LP-168 demonstrates a encouraging safety and efficacy profiles in patients with BTKi naïve R/R MCL, with high response rates, deep remissions, and durable responses.

Waterfall Plot of Subjects with R/R MCL (N = 27*)



- Non-GCB R/R DLBCL: As of February 28, 2025, being the latest cut-off date of the non-GCB R/R DLBCL cohort, 45 subjects were enrolled in the clinical trial for safety and efficacy assessments.

LP-168 demonstrated a manageable safety profile in non-GCB R/R DLBCL patients. The most common treatment-related adverse events (TRAEs) were Grade 1. The proportion of subjects experiencing $\geq$ Grade 3 TRAEs and serious treatment-related adverse events was 40.0% and 11.1%, respectively. The proportion of subjects requiring dose interruption and dose reduction due to TRAEs was 20.0% and 2.2%, respectively. No subjects experienced permanent treatment discontinuation or death due to TRAEs.

LP-168 demonstrated efficacy in non-GCB R/R DLBCL patients with an ORR of 57.8% and CR rate of 31.3%. In heavily pretreated patients who had received $\geq$ 3 prior lines of therapy (n=16), the ORR and CR rates were 68.8% and 43.8%, respectively. Among subjects receiving the Phase II recommended dose of 200mg QD or higher, the ORR and CR rates were 72.2% and 33.3%, respectively. With a median follow-up of 8.1 months, the median DOR was not reached, with a 12-month DOR rate of 64.2%. The median PFS was 7.1 months with a median follow-up of 8.1 months, and the 12-month PFS rate was 48.7%, demonstrating durable responses and disease control in this challenging patient population.

BUSINESS

- R/R MZL As of February 28, 2025, being the latest cut-off date of the R/R MZL cohort, 33 subjects were enrolled in the clinical trial for safety and efficacy assessments.

LP-168 demonstrated meaningful clinical activity in R/R MZL patients, achieving an ORR of 75.8% with 24.2% of patients achieving CR across 33 patients. Efficacy was consistent across patient subgroups, with patients who had received ≥ 2 prior lines of therapy (N=13) showing an ORR of 61.5% and CR rate of 30.8%, while those with refractory disease (N=7) achieved an ORR of 71.4% and CR rate of 28.6%. 90.9% of evaluable subjects experienced varying degrees of reduction in the SPD of target lesions following treatment with LP-168 compared to baseline. With a median follow-up of 17.9 months, the median PFS was not yet reached, with 6-month and 12-month PFS rates of 75.3% and 71.9%, respectively. The median DOR was 16.2 months with 6-month and 12-month DOR rates of 91.3% and 86.2%, respectively, demonstrating both high response rates and durable clinical benefit in this heavily pretreated population.

LP-168 demonstrated a safety profile in R/R MZL patients, with most TRAEs being Grade 1-2 in severity. The most common TRAEs ($\geq 20\%$) included neutrophil count decreased (33.3%), platelet count decreased (33.3%) and white blood cell count decreased (30.3%). No subjects experienced permanent treatment discontinuation or death due to TRAEs, supporting the manageable tolerability profile of LP-168 in this patient population.

Phase I Clinical Trial in Patients with R/R B-cell Malignancies in the United States (NCT04775745)

Trial Design. The clinical trial is a Phase I, multi-center, open-label, dose-escalation study to evaluate the safety, tolerability, PK and clinical activity of LP-168 in subjects with R/R B-cell malignancies. The primary objectives of this study are to evaluate the safety and tolerability profile of LP-168, determine the maximum tolerated dose and/or recommended Phase II dose (RP2D) for once or twice daily oral administration as a single agent, and characterize the PK profile in adult patients with relapsed/refractory B-cell malignancies, including CLL/SLL, WM, FL, MCL, MZL, DLBCL, and HCL, each being a separate cohort. Secondary objectives focus on evaluating preliminary efficacy by assessing progression-free survival (PFS), ORR, and duration of response (DOR) across these B-cell malignancies. Following determination of the maximum tolerance and establishment of the RP2D, the study will proceed to a cohort expansion phase with enrollment of additional subjects.

Trial Status. We initiated the clinical trial in August 2021, and plan to enroll 120 subjects for this clinical trial. The primary endpoints of the Phase I study for the R/R CLL/SLL cohort were met upon FDA’s confirmation on December 2, 2025 of the RP2D of rocbrutinib at 200 mg once daily. The Phase I study is subject to long-term safety and efficacy follow-up.

Trial Results. In R/R CLL/SLL, LP-168 has demonstrated encouraging efficacy compared to third-generation reversible BTK inhibitor pirtobrutinib, despite treating a more heavily pretreated patient population in its Phase I clinical trial in the United States involving 40 subjects. LP-168 was tested in a more challenging patient group — those who had received more prior treatments (four previous therapies versus three for pirtobrutinib patients). Additionally, 45% of LP-168 patients had tried two or more BTK inhibitors compared to only 14% in the pirtobrutinib study. LP-168 also included 21% of patients who had previously received non-covalent BTK inhibitors, a patient population that pirtobrutinib studies excluded entirely. LP-168 achieved remarkable response rates of 62.5% across all doses and 78.3% at the recommended ≥ 200 mg daily dose, compared to pirtobrutinib’s 65% overall response rate. LP-168 also demonstrated notably deeper responses, with 65.6% of patients achieving partial responses, as compared to 59% for pirtobrutinib. Most significantly, with a median follow-up of 30.26 months, LP-168’s median progression-free survival remains immature and is estimated at 28.1 months, substantially outperforming pirtobrutinib’s 14.0 months median PFS.

BUSINESS

Notably, LP-168’s ability to overcome treatment resistance represents a particular clinical advantage. In patients carrying the BTK T474X mutation, which confers resistance to first through third generation BTK inhibitors and serves as a primary resistance mechanism to pirtobrutinib, LP-168 achieved an 80% ORR with 100% disease control rate. Additionally, LP-168 has shown preliminary activity against the clinically significant L528W resistant mutation, with some patients maintaining responses exceeding one year, positioning LP-168 as a potentially transformative therapy for heavily pretreated CLL/SLL patients with limited treatment options. Further, only two out of 302 (0.7%) patients discontinued treatment due to adverse events. No treatment related death has occurred.

Phase II Registrational Clinical Trial in R/R MCL Patients in China (NCT05716087)

Trial design. This is an open-label, multicenter, single-arm Phase II study evaluating LP-168, in Chinese patients with R/R MCL who have failed prior covalent BTK inhibitor treatment. Eligible patients for the Phase II registrational clinical trial for R/R MCL shall have received prior BTK inhibitor treatment (i.e., not BTKi-naïve). In particular, eligible patients must have failed, relapsed following, or been intolerant to both a prior anti-CD20 antibody-containing regimen and at least one BTK inhibitor, and the protocol expressly permits the anti-CD20 antibody and the BTK inhibitor to have been administered as part of the same line of therapy. Accordingly, patients who received both an anti-CD20 antibody and a BTK inhibitor in a single prior line of treatment and subsequently experienced disease progression or intolerance are eligible for enrollment as second-line patients. The study also enrolls patients who failed or were intolerant to a BTK inhibitor and are not suitable for an anti-CD20 antibody-containing regimen. For treatment paradigm for 3L R/R MCL patients, please see “Industry Overview — Global and China BTK Inhibitor Market — Indications and Treatment Pathways for BTK Inhibitors — Maintenance and Relapsed/Refractory (“R/R”) Setting.” Patients receive LP-168 at 150mg once daily in 28-day cycles until disease progression or unacceptable toxicity, with the primary endpoint being overall response rate assessed by an independent review committee using Lugano 2014 criteria, and secondary endpoints including safety, quality of life, pharmacokinetics, and additional efficacy parameters such as complete response rate, progression-free survival, overall survival, duration of response, and time to response. The follow up period is 6 months after the last patient was enrolled. A total of 62 subjects were enrolled in this clinical trial, with 61 subjects evaluable for efficacy.

Trial status. The first patient was enrolled in May 2023. As of December 5, 2024, being the cut-off date of primary endpoint for this clinical trial, all primary endpoints have been reached and the clinical trial is completed. Clinical trial results of this trial were used to support the NDA application for LP-168.

Efficacy data. Clinical trial as of the cut-off date demonstrated encouraging efficacy profile of LP-168 in the treatment of R/R MCL. The ORR was 63.9%, with a CR of 19.7%. The median time to initial response was 1.84 months. As of the cut off date, 90.6% of the subjects with disease control experienced tumor regression based on SPD measurements. The median progression-free survival (PFS) was 7.39 months, with 6-month PFS rate of 53.3% and 12-month PFS rate of 46.1%. As of the cut-off date, the median duration of response had not been reached, with 73.1% of responders maintaining response at 6 months and 67.5% at 12 months.

Safety data. LP-168 demonstrated a manageable safety profile in 62 subjects with R/R MCL. Serious adverse events (SAEs) were reported in 37.1% of subjects, of which 17.7% were considered related to LP-168, with the most common drug-related SAEs being infections such as pneumonia (8.1%), upper respiratory tract infection (1.6%), viral pneumonia (1.6%), and urinary tract infection (1.6%). While treatment-emergent adverse events (TEAEs) were reported in 96.8% of subjects, drug-related Grade 3 or higher adverse events (TRAEs) occurred in 38.7% of subjects, with the most frequent events of special interest in any grade including platelet count decreased (43.5%), anemia (30.6%), neutrophil count decreased (29.0%), and pneumonia (19.4%) and white blood cell count decrease (14.5%). Treatment interruptions, which were observed in 33.9% of patients, were effectively managed through standard dose modifications and supportive care, allowing for continued therapy and dose reductions were required in only 3.2% of subjects. No treatment-related permanent discontinuations or deaths were reported in China, indicating that while adverse events were common, they were generally manageable with temporary dose interruptions and supportive

BUSINESS

care. We believe this manageable tolerability profile is consistent with the known safety profile of the BTK inhibitor class and supports a favorable benefit-risk assessment for the potential regulatory approval and continued development of LP-168.

Ongoing Phase III Clinical Trial in 2L R/R MCL Patients (BTKi naïve) (the “Additional Registrational Clinical Trial”)

We submitted the clinical trial protocol for this trial to the CDE in December 2025. After receiving the CDE’s confirmation, in January 2026, we initiated a randomized, controlled, head-to-head Phase III clinical trial for LP-168. This trial is expected to cover second-line R/R MCL patients (BTKi-naïve) and was initiated based on data obtained from the BTKi-naïve cohort in the Phase I clinical trial involving patients with R/R B-cell lymphoma in China. It is designed to fulfill the regulatory requirements for a confirmatory study in connection with our conditional NDA for the MCL indication. Through the Additional Registrational Clinical Trial, we also strategically advance the clinical development of LP-168 from third-line R/R MCL patients (post-BTKi) to 2L R/R MCL patients (BTKi-naïve), thereby broadening the target patient population. Specifically, this Phase III, randomized, open-label study compares LP-168 against the investigator’s choice of a standard-of-care BTKi, which may include ibrutinib, acalabrutinib, zanubrutinib, or orelabrutinib, anticipating enrollment of approximately 394 subjects.

As of the Latest Practicable Date, we were actively enrolling patients for the Additional Registrational Clinical Trial in China. We currently expect this clinical trial to be completed in 2031.

Ongoing Phase II Registrational Clinical Trial in 3L R/R non-GCB DLBCL (post BTKi) Patients

Based on our communications with the NMPA, the NMPA confirmed that the DLBCL cohort clinical trial results from the Phase I clinical trial of LP-168 in China can support the initiation of a Phase II registrational clinical trial for patients with R/R non-GCB DLBCL who received prior BTK inhibitor treatment. The NMPA acknowledged the clinical rationale and study design, and did not request additional preclinical or clinical data prior to initiation of the Phase II trial. In November 2025, we initiated an open-label, randomized controlled, multicenter Phase II clinical study primarily evaluating the efficacy and safety of LP-168 monotherapy compared to the investigator’s choice of a BR/R2 regimen in patients with non-GCB DLBCL. We expect to complete the Phase II registrational clinical trial in 3L R/R non-GCB DLBCL patients by the end of 2028.

Ongoing Phase III Clinical Trial in 2L R/R CLL/SLL (post BTKi) Patients

We submitted the clinical trial protocol and the then available clinical trial data to the FDA in April 2025. In particular, we submitted safety, efficacy, PK, and PD data from over 300 patients across China and the United States, demonstrating a strong safety and efficacy profile. Considering the totality of the clinical evidence, including the favorable benefit-risk profile, dose justification, consistency of PK/PD findings, and the significant unmet medical need in the target population, the FDA then confirmed that we may proceed with this clinical trial in July 2025. The regulatory basis for us to proceed from Phase I clinical trial directly to the Phase III clinical trial is established through the FDA’s review of our clinical development plan and trial protocols across a series of formal regulatory interactions. Specifically, we held a Type C Guidance meeting with the FDA in July 2025 to discuss the Phase II/III clinical development of rocbrutinib, followed by a second Type C meeting in November 2025 focused specifically on the global Phase III head-to-head study design (rocbrutinib vs. pirtobrutinib). Throughout this process, we submitted comprehensive clinical data and study protocols to the FDA. Between June 2025 and March 2026, we promptly addressed all FDA information requests and non-hold comments — including those relating to cardiac safety, statistical design, and prior BCL2 inhibitor use — culminating in the submission of the revised Phase III clinical trial protocol under the existing IND. The FDA reviewed our Phase III protocol and did not issue a clinical hold at any stage of the review process. In addition, we obtained the IRB (Institutional Review Board) approval for the Phase III trial in 2L R/R CLL/SLL (post BTKi) patients on April 23, 2026. Accordingly, we are permitted to proceed with the Phase III clinical trial in the United States.

BUSINESS

Accordingly, we initiated a Phase III clinical trial in 2L R/R CLL/SLL (post BTKi) patients in the United States in January 2026. In addition, the first patient was enrolled in May 2026. This is a Phase III, randomized, open-label, multicenter study designed to compare LP-168 against pirtobrutinib in adult participants with R/R CLL or SLL who have previously received a covalent Bruton’s tyrosine kinase inhibitor. We anticipate randomizing approximately 306 participants in a 1:1 ratio to receive either 200 mg of LP-168 or 200 mg of pirtobrutinib, both administered orally once daily. The treatments will be administered continuously in 28-day cycles until the occurrence of disease progression, unacceptable toxicity, withdrawal of consent, or the meeting of other specified discontinuation criteria. The primary endpoint of the trial is progression-free survival as assessed by an independent review committee. Key secondary objectives include overall survival, overall response rate, time-to-event outcomes, and safety and tolerability, while exploratory objectives encompass health-related quality of life and biomarker assessments. We expect to conduct interim analysis of this clinical trial in 2029 and complete this clinical trial in 2030. Subject to the results of the interim analysis, we may seek to submit its NDA application for this indication to the FDA in the first half of 2030.

Clinical Trial for Combination Therapy

In addition to the major clinical trials above, we also initiated the following major clinical trials with LP-168 for combination therapy, in the field of oncology, details of which are summarized in the table below.

Trial Registration Number	Phase	Study Design	Sites	Subjects	Status	Anticipated patient enrollment	Start Time	Completion Time
NCT06251180 . .	Ib ⁽²⁾	A Phase Ib Study to Assess Safety and Preliminary Efficacy of Rocbrutinib in Combination with R-CHOP ⁽¹⁾ in Patients with Newly Diagnosed B-NHL	3 sites in China	Adult patients with newly diagnosed, previously untreated B-cell Non-Hodgkin Lymphoma (DLBCL, MCL and MZL)	Ongoing	112	April 2024	By the end of 2029
NCT06978088 . .	II ⁽³⁾	A Multicenter Parallel 2 Cohort Phase II Study of LP-168 and Obinutuzumab for Previously Treated, and T474 Gatekeeper Mutant Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) and Variants of This	1 site in the U.S.. We are planning to establish an additional clinical trial center.	1) previously treated, and 2) BTK T474I mutated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) patients	Ongoing	34	June 2025	Third quarter of 2026

Notes:

- (1) We currently source the majority of the components of the R-CHOP regimen from a wholly owned subsidiary of a leading multinational biopharmaceutical company under a framework supply agreement, which helps ensure consistent quality and supply stability. The remaining component of the R-CHOP regimen are procured from other qualified suppliers. All procurement arrangements are conducted on a batch-by-batch, on-demand basis in accordance with the terms of the relevant supply agreements. To mitigate relevant risks, we have secured contractual commitments from the supplier regarding delivery delay penalties without valid reasons and advance notice of any anticipated supply disruption. We believe that the protective contractual provisions under our framework supply agreement, together with their ample production capacity, ensure a reliable and sufficient supply for our clinical trials. In addition, multiple alternative R-CHOP products are commercially available in Chinese mainland, providing us with readily accessible backup sources should the need arise, and accordingly we do not consider there to be any meaningful supply risk in practice. As confirmed by CIC, R-CHOP is widely available in the China market. In addition, we also plan to identify and qualify alternative suppliers to enable a timely transition should the need arise. Our Directors have assessed the supply arrangements for R-CHOP and, having regard to the mitigation measures in place and the general availability of these widely used pharmaceutical products, are of the view that no material supply risk currently exists, though we will continue to actively monitor our sourcing position and advance the qualification of alternative suppliers to further safeguard the continuity of our operations.

BUSINESS

- (2) We obtained the IND approval from the NMPA on April 10, 2024. Such approval was based on data generated from the MZL cohort of the LP-168 Phase I study conducted in China.
- (3) This study is an investigator-initiated trial for which the FDA granted IND approval on October 11, 2024. Such approval was based on data generated from the R/R CLL/SLL cohort of the LP-168 Phase I study conducted in the United States.

Clinical Development Plan

As of the Latest Practicable Date, our most advanced LP-168 program was its use in R/R MCL patients, for which we have submitted the NDA application to the NMPA in May 2025. In light of the clinical results, we intend to continue exploring the potential of LP-168 in R/R MCL patients without prior BTK treatments (i.e., BTK naive patients) to broaden the application of LP-168 in the treatment of R/R MCL. In January 2026, we initiated a Phase III head-to-head Additional Registrational Clinical Trial in China evaluating LP-168 versus approved BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib, or orelabrutinib) for R/R MCL, anticipating enrollment of approximately 394 subjects. We are also advancing clinical trials for LP-168 in other oncology indications. For example, LP-168 was granted Breakthrough Therapy Designation for the treatment of R/R non-GCB DLBCL in May 2024. We initiated the Phase II registrational trial design for R/R non-GCB DLBCL for LP-168 in November 2025 and currently plan to submit the NDA in 2027.

We are also advancing the development of LP-168 for other indications, such as R/R CLL/SLL. We initiated a global Phase III head-to-head trial of LP-168 against approved non-covalent BTK inhibitor, Jaypirca (pirtobrutinib), in R/R CLL/SLL patients in January 2026 to support its global registration, including China, the United States, EU and Australia. In addition, the first patient was enrolled in May 2026. The clinical trial is a randomized, open-label, multicenter study comparing LP-168 versus pirtobrutinib in adult participants with R/R CLL/SLL patients, who have previously received a covalent BTK inhibitor treatment. Approximately 306 participants will be randomized 1:1 to receive rocabrutinib 200 mg orally once daily or pirtobrutinib 200 mg orally once daily, administered continuously in 28-day cycles until disease progression, unacceptable toxicity, withdrawal of consent, or other discontinuation criteria are met. The primary endpoint is progression-free survival (PFS) assessed by an independent review committee. Key secondary objectives include overall survival, overall response rate, time-to-event outcomes, and safety/tolerability; exploratory objectives include health-related quality of life and biomarker assessments. We plan to complete subject enrollment by the end of 2027 and submit NDA application to the FDA for this indication in the first half of 2029. We have allocated [REDACTED]% of the [REDACTED] from this [REDACTED] to this global Phase III head-to-head clinical trial. For details, see “Future Plans and [REDACTED] — [REDACTED].”

In addition, in November 2025, we have initiated an open-label, randomized controlled, multicenter Phase II clinical study primarily evaluating the efficacy and safety of LP-168 monotherapy compared to the investigator’s choice of BR/R2 regimen in patients with non-GCB DLBCL. The clinical trial is expected to enroll approximately 150 subjects. As of the Latest Practicable Date, we were actively enrolling patients for this clinical trial in China.

Besides the aforementioned development plans, we will continue to formulate clinical development plans for LP-168 either as a monotherapy or as part of a combination therapy in other hematological malignancies, such as B-NHL and MZL. As we have obtained the IND approval from the NMPA for the combination therapy of LP-168 and LP-108 in mature B-cell neoplasms, we are outlining a clinical development plan for this combination therapy, which we expect to deliver deep and durable responses for multiple B cell malignancies, such as CLL/SLL and other non-Hodgkin lymphomas. Since we have developed both LP-168 and LP-108 in-house, we are not dependent on any third-party licensor for the supply of either drug substance. We primarily sourced LP-168 and LP-108 from our CDMOs, which we have entered into framework supply agreement.

BUSINESS

Beyond hematological malignancies, we will monitor the clinical development progress and prospect of LP-168 in various autoimmune diseases and formulate plans and formulate plans for unlock its potential in those indications in areas outside of Chinese mainland, Hong Kong, Macau and Taiwan.

Material Communications with Competent Authorities

China

We submitted the IND application for LP-168 to the NMPA in December 2020 and obtained its IND from the NMPA in March 2021. Since then, we had rapidly advanced its clinical development in China, primarily as a monotherapy for oncology. The IND is an umbrella IND, which does not require us to seek CDE’s approval for Phase II clinical trials. However, the CDE advised us to seek their confirmation prior to utilizing any clinical trial as the registrational trial to support our NDA submission.

We completed the MCL cohort of the Phase I clinical trial in China in patients with R/R B-cell lymphoma (NCT04993690). To expedite clinical development, we initiated a Phase II clinical trial in patients with MCL, enrolling the first patient in May 2023. Pursuant to the March 2023 Technical Guidelines, with the IND approval, the sponsor shall, prior to conducting a subsequent phase of a clinical trial, develop a corresponding clinical trial protocol, conduct the trial after obtaining approval of the ethics committee, and submit the corresponding clinical trial protocol and supporting documents on the website of the CDE for filing; provided that no additional IND approval is required. Accordingly, our Phase II trial was conducted under the scope of the previously cleared IND and did not require a separate IND approval, in compliance with applicable PRC regulatory requirements. Concurrently, with the intention of utilizing this Phase II trial to support our NDA submission for LP-168 in R/R MCL, we sought regulatory guidance from the CDE. In July 2023, we submitted a Type II meeting (EOP1) request to the CDE, including all available clinical data for LP-168 in R/R MCL, particularly data from the post-BTKi R/R MCL population. Based on these clinical trial results, CDE confirmed in a written response in September 2023 that we may proceed with a next-phase single-arm study in patients with R/R MCL who had previously received immunotherapy containing CD20 monoclonal antibody and BTK inhibitor treatment as a registrational Phase II study to support the NDA application of LP-168. The CDE also provided suggestions regarding the clinical trial protocol, including inclusion criteria, requirements for previous BTK treatment history, and the null hypothesis of the trial. Accordingly, we launched the Phase II clinical trial of LP-168 in participants with R/R MCL in China (NCT05716087).

Following completion of the Phase II clinical trial (NCT05716087), we submitted a pre-NDA meeting request to the CDE in early 2025, with the six-month follow-up assessment results. The CDE confirmed in a written response in May 2025 that we may proceed with the NDA application for LP-168 to the NMPA for the treatment of R/R MCL. Accordingly, we submitted the NDA application for LP-168 for the treatment of R/R MCL to the NMPA in May 2025, which was accepted by the NMPA in May 2025. We currently expect to obtain NDA approval by June 2026, based on the customary regulatory review period for comparable drug candidates. The NDA would allow us to commercialize LP-168 in Chinese Mainland in the third-line or later setting to treat R/R MCL patients who have previously received immunotherapy containing CD20 monoclonal antibody and BTK inhibitor treatment.

Pursuant to the March 2023 Technical Guidelines, we expect that the NDA for LP-168, if approved by the CDE, will be an NDA subject to the completion of the Additional Registrational Clinical Trial. We expect the conditional approval for LP-168 to be for the treatment of adult patients with R/R MCL who have received at least two prior systemic therapy, including a BTK inhibitor, positioning the product as a third-line, post-BTKi treatment option. The conditional approval will be based on overall response rate and duration of response data derived from a single-arm clinical trial, with full NDA approval contingent upon the results of the Additional Registrational Clinical Trial. LP-168 may be marketed and commercialized in the PRC for the

BUSINESS

approved indication on the same basis as a fully approved drug, without any restriction on commercial sale, pricing, or patient access upon conditional approval. The conditions for the Additional Registrational Clinical Trial require us to complete a confirmatory study and meet its primary endpoints. Such confirmatory study may consist of a randomized, controlled registrational clinical trial, or alternatively, a single-arm clinical trial conducted in a larger patient population with an extended follow-up period, as agreed with the CDE. As requested by the CDE pursuant to the March 2023 Technical Guidelines, the Additional Registrational Clinical Trial shall be initiated prior to the granting of the conditional NDA. In December 2025, we submitted the protocol for the Additional Registrational Clinical Trial to the CDE. In January 2026, after obtaining the CDE’s confirmation we initiated a Phase III head-to-head Additional Registrational Clinical Trial in China evaluating LP-168 versus approved BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib, or orelabrutinib) for R/R MCL, anticipating enrollment of approximately 394 subjects (NCT07377578). This Additional Registrational Clinical Trial is expected to cover second-line R/R MCL patients (BTKi-naïve) and was initiated based on data obtained from the BTKi-naïve cohort in the Phase I clinical trial involving patients with R/R B-cell lymphoma in China. The first patient was enrolled in February 2026 for this trial. The Additional Registrational Clinical Trial is expected to be completed in 2031, upon which we expect to obtain the full NDA approval. In the event that we fail to establish favorable safety and/or efficacy profiles in such Additional Registrational Clinical Trials, our conditional NDA for LP-168 may be revoked. For details, please see “Risk Factors — Risks Relating to the Development and Clinical Trials of our Drug Candidates — The NDA for our Core Product, LP-168 may be granted on a conditional basis, which imposes ongoing post-approval obligations. Failure to fulfill certain conditions could result in the revocation of our NDA approval, which would materially and adversely affect our business.”

United States

We submitted the IND application for LP-168 to the FDA in December 2020 and obtained its IND from the FDA in January 2021. Since then, we held various communications with the FDA regarding the clinical development plan and clinical trial protocol of LP-168 in the United States. The FDA raised certain comments regarding our clinical trial design, such as the dosing escalation design of our clinical trials and we had no difficulties in addressing their comments. We have obtained the FDA’s clearance for a registrational clinical trial of LP-168 for patients with 2L R/R CLL/SLL (post BTKi) in July 2025 and have initiated such clinical trial in January 2026. In addition, the first patient was enrolled in May 2026.

Autoimmune Diseases

LP-168 is poised to create significant value by expanding beyond oncology into the large and fast-growing autoimmune disease market. In December 2022, we completed the Phase I clinical trial involving 70 healthy subjects in China to evaluate the safety, tolerability, and pharmacokinetics of LP-168 to support future studies in autoimmune diseases. In Phase I clinical trial in healthy subjects, LP-168 demonstrated a safety profile at 12.5mg-75mg QD with no grade 2 or higher TRAEs observed, while achieving near-complete BTK target occupancy (~100%) at 2 hours after a single 12.5mg dose that sustained for over 24 hours. The clinical trial results demonstrated that LP-168 was well-tolerated in healthy subjects, providing a strong foundation to support subsequent therapeutic development in autoimmune indications. As of the Latest Practicable Date, our collaborator Hansoh Pharma has initiated clinical studies for LP-168 in chronic spontaneous urticaria CSU with plans to expanded into additional autoimmune indications.

BUSINESS

In August 2024, we entered into a license agreement with Hansoh Pharma, a biopharmaceutical company incorporated in the Cayman Islands, whose shares are listed on the Hong Kong Stock Exchange (stock code: 3692). Pursuant to the LP-168 License Agreement, we have granted Hansoh Pharma the exclusive right to research, develop, register, manufacture and commercialize LP-168 for non-oncology indications in Chinese mainland, Hong Kong, Macau and Taiwan. In November 2025, we further entered into a supplementary agreement with Hansoh Pharma for us to serve as the sponsor for a Phase II clinical trial in the MS indication within the aforementioned territories. For details, see “— Licensing Agreement.” We will retain all research, development and manufacturing rights, as well as commercialization rights for all the indications, including non-oncology indications, outside of the Greater China region.

LP-168 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED

LP-108 — Phase II-ready Bcl-2 Inhibitor

LP-108 is our Phase II-ready Bcl-2 inhibitor internally developed from the BeyondX Oral MedChem Platform. LP-108 is a highly selective and orally bioavailable oral Bcl-2 inhibitor. It targets the intrinsic apoptotic pathway, which is often dysregulated in cancer cells, allowing them to survive and proliferate. As of the Latest Practicable Date, we had completed the Phase I clinical study for LP-108 in patients with R/R B-cell Lymphoma in China. We plan to initiate its Phase II clinical trial in China in R/R CLL/SLL. In addition, we are developing LP-168 and LP-108, a Bcl-2 inhibitor, as a combination therapy for mature B-cell neoplasms, having obtained IND approval from China’s NMPA, and believe this infusion-free, chemotherapy-free regimen has the potential to become a front-line treatment across multiple B-cell malignancies.

Drug Design and Mechanism of Action

Bcl-2 is a key anti-apoptotic protein that plays a crucial role in regulating programmed cell death by preventing mitochondrial outer membrane permeabilization and subsequent cytochrome c release. Under normal physiological conditions, Bcl-2 family proteins maintain a delicate balance between pro-apoptotic proteins (such as BAX, BAK, BIM, and PUMA) and anti-apoptotic proteins (including Bcl-2, Bcl-xL and MCL-1) at the mitochondrial membrane. In many hematologic malignancies, particularly CLL and certain lymphomas, Bcl-2 is over-expressed, creating an imbalance that allows cancer cells to evade apoptosis and survive inappropriately.

LP-108 selectively binds to the Bcl-2 protein and displacing pro-apoptotic proteins that were previously sequestered, thereby restoring the cell’s ability to undergo apoptosis. This mechanism is particularly effective in Bcl-2-dependent tumors, where cancer cell survival is heavily reliant on Bcl-2’s anti-apoptotic function, leading to selective tumor cell death while sparing normal cells that rely on alternative survival pathways.

Market Opportunity and Competition

As of the Latest Practicable Date, AbbVie’s Venetodax was the only Bcl-2 inhibitor approved by the FDA. In addition, as of the same date, there were only two Bcl-2 inhibitors approved by the NMPA, namely AbbVie’s Venetodax and Ascentage’s Lisaftoclax. As of the same date, there were six Bcl-2 inhibitor candidates under NMPA-registered clinical trial development in China.

Summary of Clinical Development

We obtained the IND approval for LP-108 from the NMPA in February 2020 and from the FDA in September 2019. As of the Latest Practicable Date, we have initiated three clinical trials with LP-108 targeting CLL/SLL patients, including both monotherapy and combination therapy, with one trial conducted in China and two trials in the United States. As of the Latest Practicable Date, we had completed the Phase I study to evaluate the safety, tolerability, pharmacokinetics and efficacy of LP-108 in in patients with R/R B-cell Lymphoma in China (NCT04356846). To date, we have obtained the preliminary trial results for CLL/SLL patients in this trial.

BUSINESS

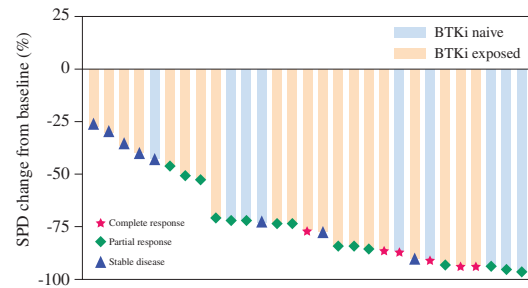
During this clinical trial, LP-108 demonstrated encouraging safety and efficacy results in 33 enrolled CLL/SLL patients treated at doses ranging from 20-800 mg/day, with a median age of 60 years and median of 2 prior therapies, including 66.7% who had received at least one BTK inhibitor. The overall response rate was 74.2% (23/31) in evaluable patients treated at doses ≥ 200 mg/day, with 16.1% achieving peripheral blood minimal residual disease (MRD) negativity and 3.0% achieving bone marrow MRD negativity. Notably, in the BTK inhibitor-experienced subset, LP-108 achieved a 70% response rate with an 84.1% 12-month progression-free survival rate and 92.9% 9-month duration of response rate, with median PFS and DOR not yet reached after a median follow-up of 14.1 months, demonstrating durable responses in this challenging patient population.

Efficacy summary and best response of patients with R/R CLL/SLL (N = 31)

Efficacy	CLL/SLL patient without prior BTKi (N = 11)	CLL/SLL patient with prior BTKi (N = 20)
Response, n (%)		
CR/CRi n (%)	2 (18.2%)	4 (20.0%)
PR n (%)	7* (63.6%)	10 (50.0%)
SD n (%)	2 (18.2%)	6 (30.0%)
PD n (%)	0 (0.0%)	0 (0.0%)
ORR n (%)	9 (81.8%)	14 (70.0%)
DCR n (%)	11 (100.0%)	20 (100.0%)
mDOT (range), months	22.4 (17.9-33.3)	11.4 (3.1-25.9)
mTTR (range), months	1.8 (1.6-11.2)	1.7 (1.6-3.7)
Median prior lines (range)	1 (1-3)	2 (1-5)

*2 patients were not evaluated as CR/CRi due to missing data of bone marrow assessment

Waterfall plot of max change in target lesion SPD from baseline (N = 29)



The safety profile was manageable with grade 3-4 treatment-related adverse events in 33 enrolled CLL/SLL patients, primarily consisting of hematological toxicities including neutropenia (34.9%), thrombocytopenia (15.8%), anemia (14.3%), and leukopenia (12.6%), with only laboratory tumor lysis syndrome observed (6.3%) and no clinical TLS events despite rapid dose escalation.

Material Communications with Competent Authorities

China

Monotherapy

We submitted the IND application for LP-108 to the NMPA in November 2019 and obtained its IND approval from the NMPA in February 2020.

We conducted a Phase I clinical trial of LP-108 in China (NCT04356846). The trial enrolled 33 patients with R/R CLL/SLL, with a median age of 60 years and a median of two prior lines of therapy. Among 31 evaluable patients receiving doses of 200 mg or above, the overall response rate was 74.2%, with complete response rates of approximately 20% and 18.2% in the BTK inhibitor-exposed and BTKi-naïve subgroups, respectively. Notably, the BTKi-naïve subgroup achieved an overall response rate of 81.8%, while previously exposed patients achieved an overall response rate of 70%. The trial was completed on April 30, 2024.

Following its completion, we submitted a Type II meeting (EOP1) request to CDE with all available clinical trial data for LP-108 in the treatment of R/R CLL/SLL patients, particularly the results obtained from the post BTKi R/R CLL/SLL population in October 2023. Based on these clinical trial results, CDE confirmed in a written response in December 2023 that we may proceed with a next-phase single-arm study in patients with R/R CLL who had previously received immunotherapy containing CD20 monoclonal antibody and BTK inhibitor treatment as a registrational Phase II study to support the NDA application of LP-108 based on the monotherapy Phase I clinical trial in China in patients with R/R B-cell lymphoma. The CDE also provided suggestions regarding the clinical trial protocol, including inclusion criteria, requirements for previous BTK treatment history, and the null hypothesis of the trial. We plan to initiate its Phase II clinical trial in China in June 2026.

BUSINESS

Combination Therapy

Beyond monotherapy, we also intend to explore the potential of LP-108 and LP-168 as a combination therapy. To that end, we obtained the IND approval from the NMPA in June 2023 and plan to initiate a Phase I/II clinical trial in China by June 2026.

FDA

In addition, we also obtained its IND application from the FDA in September 2019. In July 2020, we initiated a Phase I, multicenter, open-label, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, and clinical activity of orally administered LP-108, both as a monotherapy and in combination with azacitidine, in adult patients with relapsed or refractory myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML), and acute myeloid leukemia (AML). The primary objectives of this trial are to assess the safety and tolerability profile, determine the maximum tolerated dose and the recommended Phase II dose, and characterize the pharmacokinetic profile of LP-108 under both dosing regimens. Furthermore, the secondary objectives focus on evaluating preliminary efficacy metrics, including overall response rate, progression-free survival, duration of response, and overall survival. As a Bcl-2 inhibitor, LP-108 has therapeutic applicability across both lymphoid and myeloid malignancies because the Bcl-2 protein is overexpressed in, and promotes the survival of, malignant cells in both CLL/SLL and myeloid malignancies such as MDS, CMML and AML — a dual rationale validated by the regulatory approval of venetoclax, a structurally related Bcl-2 inhibitor, for both CLL and AML in major jurisdictions. As of the Latest Practicable Date, we had completed the U.S. Phase I trial and were in the process of evaluating the data generated therefrom. However, based on our current clinical development strategy and strategic resource allocation, we do not plan to immediately advance the clinical development of LP-108 for these specific indications at this time, allowing us to prioritize our focus on other core clinical programs.

Clinical Development Plan

As of the Latest Practicable Date, we had completed the Phase I clinical study for LP-108 in patients with R/R B-cell Lymphoma in China. We plan to initiate its Phase II clinical trial in China by June 2026.

We are also exploring opportunities for LP-108 in combination therapies with other drugs, including our LP-168. We are conducting clinical trials in LP-108 in a combination therapy with azacitidine in patients with AML, MDS or CMML in China and the United States, respectively. We currently purchase azacitidine from several independent third-party suppliers and have entered into framework supply agreements to secure adequate and continuous supply to meet our projected clinical and commercial demand. We have secured contractual provisions requiring advance notice of any supply interruption or change in manufacturing capacity and incorporated contractual remedies entitling us to refunds and compensation from suppliers in the event of quality-related failures, to further safeguard the continuity and integrity of our supply. Our Directors have assessed the supply arrangements for azacitidine and are of the view that no material supply risk currently exists. We obtained the IND approval from the NMPA in June 2023. We plan to initiate the Phase I/II clinical trial for the combination therapy using LP-108 and LP-168 in China by June 2026. In addition, we obtained the FDA approval for the Phase II trial for combination therapy of LP-108 and LP-168 in March 2026. We plan to initiate the patient enrollment for this trial in the United States in the second half of 2026.

LP-108 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED

LP-118 — Phase-I-stage Bcl-2/Bcl-xL Inhibitor

Overview

LP-118 is an oral dual Bcl-2/Bcl-xL inhibitor that achieves a delicate balance between potent anti-tumor efficacy and on-target platelet toxicity. Therefore, LP-118 is able to overcome the resistance mechanisms that limit first-generation Bcl-2 inhibitors such as venetoclax. Preclinical

BUSINESS

studies have demonstrated that LP-118 maintains activity against both venetoclax-naïve and venetoclax-resistant chronic lymphocytic leukemia (CLL) cells, including those harboring the Bcl-2 G101V mutation or exhibiting Bcl-xL overexpression, two primary mechanisms of venetoclax resistance.

As of the Latest Practicable Date, we had completed the Phase I clinical study for LP-118 in patients with advanced tumors in China. In addition, we are conducting a Phase I, multi-center, open-label clinical trial with the combination therapy of LP-118 and ponatinib in R/R T-ALL/LBL in the United States. As of the Latest Practicable Date, a total of 15 patients had been enrolled across five dose levels. We expect to complete this trial by the end of 2026.

Drug Design and Mechanism of Action

LP-118 functions as a dual Bcl-2/Bcl-xL inhibitor by directly binding to the hydrophobic groove of both Bcl-2 and Bcl-xL proteins. LP-118 displaces pro-apoptotic proteins that are normally sequestered by Bcl-2 and Bcl-xL, thereby liberating them to initiate the apoptotic cascade. This displacement leads to the activation of BAX and BAK proteins, which oligomerize and form pores in the mitochondrial outer membrane, resulting in mitochondrial outer membrane permeabilization. The subsequent release of cytochrome c and other mitochondrial proteins activates the caspase cascade, ultimately leading to cancer cell death through the intrinsic apoptotic pathway. The dual targeting approach of LP-118 provides significant advantages over single-target Bcl-2 inhibitors, particularly in addressing resistance mechanisms that commonly emerge during treatment. By simultaneously inhibiting both Bcl-2 and Bcl-xL, LP-118 prevents cancer cells from switching their survival dependence from one anti-apoptotic protein to another, thereby closing off primary escape routes and maintaining therapeutic efficacy even in the presence of these resistance mechanisms. This dual inhibition strategy also expands the therapeutic window to cancer types that primarily depend on Bcl-xL for survival, such as certain solid tumors and acute lymphoblastic leukemia, which are typically resistant to Bcl-2-selective inhibitors.

Summary of Clinical Development

We obtained the IND approval for LP-118 from the NMPA in May 2021 and from the FDA in February 2021. As of the Latest Practicable Date, we were conducting three clinical trials with LP-118 targeting SCLC, NHL, hematologic tumors and T-ALL/LBL in China and the United States, respectively and we had obtained preliminary clinical trial data from its Phase I clinical trial on safety, tolerance, pharmacokinetics and preliminary efficacy of LP-118 in patients with advanced malignancies in China (NCT05025358).

In September 2021, we initiated the Phase I clinical trial for LP-118 in patients with advanced tumors (including 2L-3L SCLC, 2L+ R/R NHL) in China. We completed this trial in March 2026 and are currently conducting data analysis. The clinical trial is a Phase I, multi-center, open-label dose escalation study, which enrolled 68 subjects with advanced malignancies including metastatic solid tumors and relapsed/refractory B-cell and T/NK-cell lymphomas to assess LP-118's safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity. The trial follows a standard Phase I design with dose escalation to determine the MTD and RP2D, followed by a dose expansion cohort in specific disease types once the optimal dosing is established. This comprehensive approach allows for systematic evaluation of LP-118's therapeutic potential across diverse cancer types while establishing the foundation for future Phase II clinical trials.

Generally, LP-118 demonstrated an encouraging efficacy and safety profile in this trial. LP-118 has demonstrated exceptional therapeutic potential in SCLC, a highly aggressive neuroendocrine tumor with rapid progression and limited treatment options. LP-118 achieved an ORR of 13.9% and DCR of 69.4%. The most common adverse events were hematological, with white blood cell count decrease, lymphocytopenia, and anemia each occurring in over half of patients (52.5% each), while grade 3 or higher severe adverse events were relatively infrequent, with lymphocytopenia being the most common severe hematological AE (30.0%) and hyponatremia the most common severe non-hematological AE (10.0%).

BUSINESS

Next Steps

We completed the Phase I clinical trial with LP-118 in patients with advanced tumors (including 2L-3L SCLC, 2L+ R/R NHL) in China in March 2026. We are conducting a Phase I clinical trial in patients with R/R HM in the United States with LP-118 involving up to 100 patients. As of the Latest Practicable Date, we have enrolled 27 patients for this trial in the United States. In addition, we are conducting a clinical trial with the combination therapy of LP-118 and ponatinib in R/R T-ALL/LBL in the United States and a total of 15 patients have been enrolled across five dose levels as of the Latest Practicable Date. We expect to complete this trial by the end of 2026. We currently procure ponatinib from several independent third-party suppliers located across the United States, and have entered into framework supply agreements with each supplier to secure adequate and continuous supply to meet our projected clinical and commercial demand. The diversification of our supplier base mitigates the risk of single-source dependency and reduces our exposure to regional supply chain disruptions, regulatory changes or geopolitical developments affecting any one market. Our Directors are of the view that no material supply risk currently exists. In addition, we obtained IND approval from the FDA for LP-118 in February 2026 for a Phase I study of the Bcl-2/Bcl-XL inhibitor LP-118 in combination with ponatinib, dexamethasone and blinatumomab in adults with newly diagnosed Ph+ ALL, and the study is planned to be initiated in the second half of 2026.

LP-118 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED

Other Preclinical Drug Candidates

We are developing a pipeline of PROTACs targeting high-value oncology indications with significant market opportunities. Our lead programs include NW-7-354, a BTK PROTAC, NW-8-461, an MDM2 PROTAC, and NW-22-159, a KRAS PROTAC. Our BeyondX Oral MedChem Platform’s ability to design selective, orally bioavailable PROTACS, positioning us to capture significant value across these large, underserved markets while establishing a sustainable competitive advantage through our differentiated approach.

THE BEYOND X ORAL MEDCHEM PLATFORM

Lipinski’s Rule of Five is a widely applied empirical guideline in the development of oral small-molecule drugs. It sets threshold values for properties such as molecular size, polarity, and lipophilicity to predict how well a compound might be absorbed and utilized in the human body. For details, see “Industry Overview — Overview of Modern Drug Discovery or Bioavailable Small Molecule Medicine.” Although the Rule of Five is widely used in small-molecule drug development, it has significant inherent limitations. It is increasingly recognized in the industry that drug discovery should not be confined to the Rule of Five’s scope. In response to this, we have established our BeyondX Oral MedChem Platform. The key competitive advantages of our bRo5 drug candidates primarily include encouraging pharmacokinetics, high potency and efficacy, and good selectivity and safety.

- ***Covalent & Non-covalent Sub-platform.*** We have independently developed the “covalent & non-covalent” dual-mechanism drug design platform. This platform has made important advances in covalent targeted therapy. It enables a single drug molecule to autonomously switch its mechanism of action based on the gene mutation status of tumor cells. This dual-mechanism approach effectively addresses major industry challenges caused by tumor heterogeneity — such as low clinical response rates, short progression-free survival, and limited patient populations. The “covalent & non-covalent” drug design platform has already achieved clinical proof-of-concept (POC) through the BTK inhibitor. Furthermore, this platform can be applied not only to BTK but also to other covalent targets such as EGFR, KRAS, JAK, and FGFR.

BUSINESS

- **Protein-Protein Interaction (PPI) Sub-platform:** Based on our BeyondX Oral MedChem Platform, our protein-protein interaction platform primarily encompasses targets such as Bcl-2, Bcl-xL, Mcl-1, and MDM2-p53. Among these targets, Bcl-xL acts as a double-edged sword. On one hand, Bcl-xL is a very important anti-cancer target that is often overexpressed in certain cancers. High levels of Bcl-xL can cause many drugs to lose effectiveness, leading to drug resistance. On the other hand, Bcl-xL is essential for the survival of platelets. Excessive inhibition of Bcl-xL can cause thrombocytopenia (low platelet counts), increasing the drug’s safety risks. We have taken an innovative approach by to harness Bcl-xL’s anti-cancer effects while keeping its on-target platelet toxicity under control. As a result, we achieve a delicate balance between anti-cancer activity and on-target platelet toxicity, as evidenced in the design of LP-118.
- **PROTAC Sub-platform:** We have developed a PROTAC platform. As part of this effort, we created and continue to expand a proprietary E3 Ligase Binding Moiety (EBM) — Linker library. By leveraging this library within our PROTAC platform, we aim to efficiently advance new oral treatments for patients while maintaining scientific leadership and strong intellectual property protection. This library has three key features (i) each building block in the EBM-Linker library has been validated through molecular docking to ensure it can effectively bind to an E3 ligase enzyme (ii) the building block in our library are designed with favorable oral bioavailability (iii) many building block in our EBM-Linker library have unique, innovative structures, which helps us build patent protection around our discoveries. Leveraging our PROTAC platform, we have developed three preclinical drug candidates, each targeting an oncology pathway with significant therapeutic potential. Our current pipeline includes a BTK-targeting degrader for the treatment of CLL/SLL and DLBCL, an MDM2-targeting degrader for the treatment of AML, and a KRAS-targeting degrader for the treatment of NSCLC, CRC and pancreatic cancer. All of these drug candidates are currently in the lead optimization stage of preclinical development and we expect to submit IND application in the first half of 2027.

While our BeyondX[®] Oral MedChem Platform significantly expands the druggable chemical space, it is not universally applicable to all categories of “Beyond Rule of 5” compounds. The platform currently has limitations regarding specific subclasses, such as peptide-based bRo5 molecules, for which we have not yet generated data or developed the requisite proprietary know-how.

LICENSING AGREEMENT

License Agreement with Hansoh Pharma for LP-168

In August 2024, we entered into a license agreement (the “**LP-168 License Agreement**”) with Hansoh Pharmaceutical Group Company Ltd (“**Hansoh Pharma**”), a pharmaceutical company incorporated in the Cayman Islands and listed on the Hong Kong Stock Exchange (stock code: 3692). Hansoh Pharma is one of the few innovation-driven Chinese pharmaceutical companies with an established leadership position in some of the largest and fastest-growing therapeutic areas in China with significant unmet clinical needs. Pursuant to the LP-168 License Agreement, we have granted Hansoh Pharma the exclusive right to research, develop, register, manufacture and commercialize LP-168 for non-oncology indications, including but not limited to Chronic Spontaneous Urticaria (“**CSU**”), Immune Thrombocytopenia (“**ITP**”), Multiple Sclerosis (“**MS**”), Neuromyelitis Optica Spectrum Disorders (“**NMOSD**”), Generalised Myasthenia Gravis (“**gMG**”), and Membranous Nephropathy (“**MN**”) (the “**Licensed Field**”), in Chinese mainland, Hong Kong, Macau and Taiwan (the “**Territory**”). The LP-168 License Agreement shall take effect as of the date of its execution. This agreement will remain in effect until the earlier of the following dates: (i) the expiration of the last valid claim of the Licensed Field within the Territory, or judicial invalidation thereof; or (ii) ten years following the first approval of a non-oncology indication for LP-168 in that Territory, unless the LP-168 License Agreement expires or is terminated earlier.

BUSINESS

According to the LP-168 License Agreement, we grant to Hansoh Pharma (i) an exclusive right to research, develop, register, manufacture and commercialize the LP-168 within the Licensed Field in the Territory during the term of the LP-168 License Agreement, who are solely responsible for and bears all costs associated with such activities. Therefore, Hansoh Pharma is primarily responsible for conducting clinical trials for the Licensed Field within the Territory; and (ii) to sub-license and/or subcontract its rights and obligations under the agreement for the license purpose to third-party service providers (e.g., CROs, CMOs, CDMOs) within the Licensed Field and Territory, and to its affiliates or within Hong Kong, Macau, and Taiwan, without our prior written consent. In line with the market practice, for any sublicense and/or subcontract of its rights and obligations under LP-168 License Agreement to third-party service providers (e.g., CROs, CMOs, CDMOs) within the Licensed Field and Territory that does not require our prior consent, Hansoh shall provide us with a copy or a summary of the relevant agreement within 30 days of execution.

The LP-168 License Agreement established a joint steering committee (the “JSC”) to support and oversee the overall coordination and oversight of the activities under this agreement. The JSC shall be composed of an equal number of representatives nominated by each party, unless otherwise agreed. Hansoh shall appoint three representatives, and the other party shall appoint three representatives. Each representative must have sufficient seniority and expertise in product development, manufacturing, and registration within their respective party. The JSC shall endeavor to make decisions by consensus. If consensus is not reached by the JSC, Hansoh Pharma shall have the sole authority to make the final decision with respect to any aspects by itself for the development and manufacturing of LP-168 within the Licensed Field in the Territory; while we shall have the sole authority to make the final decision with respect to any aspects for LP-168 beyond the Licensed Field in the Territory and any aspects with regard to the LP-168 outside the Territory.

We retain all rights with regard to LP-168 beyond the Licensed Field in the Territory and all rights with regard to LP-168 outside the Territory, including rights to manufacture, improve, and develop the product, as well as intellectual property rights not expressly granted under the LP-168 License Agreement.

Hansoh Pharma may terminate this agreement, without any cause, with 30 days’ prior written notice. We may terminate the LP-168 License Agreement if Hansoh Pharma fails to employ its commercially reasonable efforts to conduct any development or commercialization under this agreement for any continuous 12-month period after the Effective Date. Either party may terminate this agreement in the event of (i) the other party’s uncured material breach of this agreement with a 60 days’ prior written notice, or (ii) the other party’s liquidation, dissolution, bankruptcy, winding-up or similar insolvency proceedings. Any dispute arising from or related to the LP-168 License Agreement must first be addressed through good-faith negotiations via the JSC. If the dispute is not resolved within 30 days after negotiations begin, either party may submit it to arbitration to the Shanghai International Economic and Trade Arbitration Commission. The arbitral award will be final and binding on both parties, and, unless the tribunal decides otherwise, the losing party will bear the arbitration costs.

Under the LP-168 License Agreement, Hansoh Pharma agreed to pay us a total consideration consisting of a non-refundable upfront payment of RMB28.84 million (inclusive of VAT), which was determined with reference to arm’s length negotiation between the parties, as well as potential payments upon reaching certain R&D, regulatory and sales based commercial milestones of up to RMB701 million, including (i) a technology transfer milestone payment of RMB5.0 million, which is triggered upon completion of the production and release of the first batch by Hansoh Pharma after provision of technology transfer documents by us; (ii) regulatory milestone payments of up to RMB94.0 million, which are triggered upon: (a) the enrollment of the first patient in specified clinical trials for the first non-oncology indication; (b) the receipt of marketing approval for the first non-oncology indication; and (c) the enrollment of the first patient in specified clinical trials and the receipt of marketing approval for each subsequent non-oncology indication, up to a defined maximum number of indications in total; and (iii) sales milestone payment of up to RMB500.0 million, plus tiered royalties up to double-digit percentages on future product sales, and each sales milestone is triggered on the first occasion that the relevant annual net sales threshold of the Licensed Field is reached within the Territory. As of the Latest Practicable Date, we have received a total amount of RMB38.2 million (inclusive of VAT) from Hansoh.

BUSINESS

As CSU is one of the Licensed Fields under the LP-168 License Agreement, in April 2025, Hansoh Pharma initiated a Phase I/II clinical trial in China for LP-168 (HS-10561) in healthy subjects and CSU patients.

Supplementary Agreement with Hansoh Pharma

In November 2025, we further entered into a supplementary agreement with Hansoh Pharma (the “**Supplementary LP-168 License Agreement**”). The decision to enter into the Supplementary LP-168 License Agreement was based on a range of regulatory considerations and clinical progress of LP-168. Specially, since LP-168 has not obtained marketing approval, and in light of applicable regulatory constraints, the parties have mutually agreed that we shall serve as the sponsor for a Phase II clinical trial in the MS indication within the Territory (the “**Licensed Trial**”). As of the Latest Practicable Date, we did not plan to carve out the MS indication from the Licensed Field and did not intend to sponsor clinical trials for other indications within the Licensed Field.

Pursuant to the Supplementary LP-168 License Agreement, we are solely responsible for the overall design, execution, and funding of such trial, including the provision of investigational drugs and technical support to clinical research centers. Prior to commencing the trial, we must submit the overall trial design plan to Hansoh Pharma for prior written consent, and must thereafter periodically report on trial progress and promptly share all clinical data and results with Hansoh Pharma. We bear all costs solely in relation to the Licensed Trial and without any right of recovery, primarily in consideration of the future commercial and developmental value of the Licensed Trial data generated therefrom. We expect to complete the Licensed Trial in 2027. Hansoh Pharma has the right to request discussions with us on safety matters and to reach consensus on risk management measures, and Hansoh Pharma retains all rights and remedies as specified under the LP-168 License Agreement.

Any matters not addressed by the Supplementary LP-168 License Agreement are governed by the LP-168 License Agreement, including the payment term. In addition, the terms of the Supplementary LP-168 License Agreement prevailing in the event of any conflict, and the agreement takes effect from the date of execution by the authorized representatives of both parties.

RESEARCH AND DEVELOPMENT

We aim to utilize our industry expertise and well-established R&D capabilities to create novel and effective treatments in oncology and autoimmune diseases. We recognize that research and development are vital to our future growth and maintaining a competitive edge in the global biopharmaceutical industry. Throughout our efforts, we have developed and leveraged a comprehensive, integrated research and development strategy that encompasses target discovery, molecular identification and evaluation, translational science, and clinical development. Our technological strengths include the discovery of novel molecular structures and entities, analysis of molecular processes and quality standards, as well as the development of clinical drug combination strategies. By combining these internal capabilities with the external resources of our partners and service providers, we have positioned our pipeline products as leaders in both the Chinese and global markets.

R&D Strategy

Our research and development efforts are carried out by an internal R&D team. Our drug discovery, preclinical, and medical team collaborate closely, combining expertise across multiple disciplines such as biology, pharmacology, chemistry, toxicology, structural biology, translational medicine, and clinical research to advance our drug candidates. We have built comprehensive in-house capabilities spanning the entire drug discovery process. Our clinical development division oversees all aspects of clinical trials.

BUSINESS

In 2024 and 2025, our research and development expenses were RMB149.5 million and RMB128.7 million, respectively, accounting for 85.4% and 69.7%, in terms of our total operating expenses for the same period, respectively. Our research and development expenses decreased from RMB149.5 million in 2024 to RMB128.7 million in 2025, primarily in line with the clinical progress of our Core Product. This is primarily because we completed the Phase II registrational clinical for LP-168 in R/R MCL subjects in May 2025.

In 2024 and 2025, our research and development expenses incurred on LP-168 amounted to RMB113.6 million, and RMB92.8 million, respectively, representing approximately 76.0%, and 72.1% of our total research and development expense for the same year/period. The movement of our research and development expenses attributable to our Core Product in line with its commercialization schedule. In addition, we also engage CRO and CDMO to support our R&D activities. In 2024 and 2025, our total CRO expenses amounted to RMB49.7 million and RMB39.9 million, respectively. In the same year, our total CDMO expenses amounted to RMB25.8 million and RMB13.2 million, respectively. The breakdowns of our CRO and CDMO expenses for the relevant years are set out below.

CRO

	Year ended December 31	
	2024	2025
	(RMB'000)	(RMB'000)
LP-168	34,599	26,582
LP-118	7,262	5,378
LP-108	3,634	3,122
Other preclinical programs	4,240	4,836
Total	<u>49,735</u>	<u>39,918</u>

CDMO

	Year ended December 31	
	2024	2025
	(RMB'000)	(RMB'000)
LP-168	23,247	12,653
LP-118	1,054	9
LP-108	<u>1,476</u>	<u>577</u>
Total	<u>25,777</u>	<u>13,239</u>

The decrease of our CRO and CDMO expenses from 2024 to 2025 was primarily because we completed Phase II registrational clinical trial for LP-168 in R/R MCL patients in China (NCT05716087) in December 2024. We have submitted the NDA application to the NMPA for LP-168 for the treatment in R/R MCL in May 2025, and expect that we can receive the NDA and commence commercialization in 2026. We will continue to utilize our technology platform to advance additional novel drug candidates targeting more disease areas.

Our R&D Team

Our R&D team has strong expertise, deep understanding, and broad development experience. As of the Latest Practicable Date, 33 members of our R&D team had obtained advanced degrees, including 12 members with doctorate degrees and 21 members with master’s degrees. Our research and development team is led by distinguished scientists with extensive experience in drug

BUSINESS

development. The core R&D staff consists of six professionals specializing in the fields of chemistry, biology, pharmacology, and medicine, each possessing over 13 years of industry experience. All key personnel involved in the development of the Core Product continue to be employed by us during the Track Record Period and up to the Latest Practicable Date.

The following table sets forth the identities, positions, and expertise of our core R&D personnel as of the Latest Practicable Date and their involvement and contributions to the R&D activities, including with respect to our Core Product, up to the same date. We had not experienced any material difficulties in our R&D activities, including the research and development of our Core Product, due to the change of R&D personnel.

Name	Position	Expertise	Involvement and contributions to the R&D activities, including with respect to our Core Product	Time of joining our Group
Dr. Tan	Chairman, Chief Executive Officer, and Chief Medical Officer	Clinical development of novel anti-tumor drugs	Founded the company and, as a key leader, spearheaded the end-to-end development of our Core Products.	2018
Dr. Chen	Chief Scientific Officer	Design, CMC and preclinical development of organic small molecule drugs	Founded the company and, as a key leader, spearheaded the end-to-end development of our Core Products.	2015
Shen Yue	Senior Vice President of Clinical Development	Clinical development of novel anti-tumor drugs	Leads our China Clinical Department, orchestrating, advancing, and supporting the execution of clinical studies while contributing to the development strategy of clinical research and registration planning.	2019
Xu Xuesong	Vice President	Discovery and preclinical development of central nervous system and oncology drugs	Leads our Chemistry & CMC team, supervise R&D of the Chemistry, CMC regulatory compliance and the end-to-end preparation of technical documentation from IND to NDA submission.	2019

BUSINESS

Name	Position	Expertise	Involvement and contributions to the R&D activities, including with respect to our Core Product	Time of joining our Group
Anna Yu Chen . .	Vice President of Clinical Development, US/EU Oncology Operations	Designing and conducting clinical studies	Leads our US and EU Clinical Department, orchestrating, advancing, and supporting the execution of clinical studies while contributing to the development strategy of clinical research and registration planning.	2019
Lou Yejiang. . . .	Executive Medical Director	Diagnosis and treatment of hematological malignancies; design and conduct clinical trials	Track trends in related treatment areas, competitor development strategies, and clinical data, as well as participating in the formulation of clinical development strategies for our Core Product.	2022

Scientific Advisory Board

We have built strong relationships with renowned industry experts. We regularly engage our scientific advisory board, comprising distinguished scientists, to advise on our research strategy and clinical development plan. Our scientific advisory board is led by John C. Byrd, M.D..

- **John C. Byrd, M.D.**, is a distinguished physician-scientist in hematology and oncology. He has served as Chair of the Department of Internal Medicine and Gordon and Helen Hughes Taylor Professor of Medicine at the University of Cincinnati and will serve at the University of Pittsburgh. Dr. Byrd has led numerous landmark clinical and translational studies, particularly in chronic lymphocytic leukemia (CLL) and acute myeloid leukemia (AML) and has served as principal investigator on multiple major grants funded by the U.S. National Cancer Institute and the Leukemia & Lymphoma Society. Currently, he serves as the Chair of the Department of Internal Medicine at the University of Cincinnati. He served as the PI for Phase I study for LP-168 in R/R B cell malignancies and LP-118 in R/R heme malignancies in the U.S.. In addition, he is assigned as the leading co-PI for the upcoming LP-168 global Phase III R/R CLL study and co-chair of the JSC.
- **Jeff Sharman, M.D.**, is a hematologist-oncologist and clinical research leader with extensive experience in drug development for hematologic malignancies. He currently serves as the director of research at the Willamette Valley Cancer Institute, as well as Medical Director of Hematology Research at the US Oncology Network, where he provides care across hematologic malignancies, solid tumors, and benign hematology. With over 100 publications and more than 18,000 citations (H-index >50), Dr. Sharman

BUSINESS

has contributed to the development of FDA-approved therapies and has led Phase III clinical trials. His work includes pivotal studies in BTK inhibition, anti-CD20 therapies, and antibody — drug conjugates, with publications in high-impact journals. He currently serves in an advisory capacity, providing us with general clinical advice through periodic strategic input on scientific direction, clinical development plans, and emerging research trends.

- **Jennifer A. Woyach, M.D.**, is a leading hematologist-oncologist who specializes in treating patients with blood cancers, particularly chronic lymphocytic leukemia (CLL) and B-cell lymphomas. She also serves as a professor in the Division of Hematology at The Ohio State University. Dr. Woyach’s research focuses on targeted therapy and resistance biology in CLL, with seminal contributions to BTK inhibitor development and resistance mechanisms through investigator-initiated trials (“IIT”) (including BTK C481S and PLCG2 mutations), supported by NIH/NCI R01 and K23 awards and LLS funding, which was associated with the IITs conducted by Dr. Woyach. She served as the PI for Phase I study for LP-168 in R/R B cell malignancies and LP-118 in R/R heme malignancies in the U.S.. In addition, she is assigned as the leading co-PI for the upcoming LP-168 global Phase III R/R CLL study and co-chair of the JSC.
- **Pier Luigi Zinzani, M.D.**, is associate professor of Medicine Hematology and Chief of the clinical and translational program of the Lymphoma Unit at the Institute of Hematology and Medical Oncology “L. e A. Seràgnoli” University of Bologna, Italy. He has been a leading figure in lymphoma and leukemia research and treatment for over three decades. He has headed the clinical and translational program of the Lymphoma Unit at the Institute of Hematology and Medical Oncology. Prof. Zinzani has served as the principal investigator in more than 150 clinical trials — including international multicenter Phase I and II studies — focusing on Hodgkin lymphoma, non-Hodgkin lymphoma, and chronic lymphocytic leukemia. He is an active member of prestigious professional societies, including the American Society of Hematology and the American Society of Clinical Oncology. He currently served in an advisory capacity, providing us with general clinical advice in lymphoma and leukemia research and treatment.
- **Wendy Stock, M.D.**, is co-chair of the Leukemia Committee for the National Cancer Institute-supported Alliance for Clinical Trials in Oncology and a co-leader of the Clinical and Experimental Therapeutics research program at the University of Chicago Medicine Comprehensive Cancer Center. She also serves as an Associate Editor for Blood Advances and is a Councillor for the American Society of Hematology. She played a pivotal role in the development and national implementation of pediatric-inspired chemotherapy regimens for young adults with ALL, significantly improving survival rates in this population. She served as a PI for the LP-118 study in R/R heme malignancies and the lead PI for multiple IIT studies in ALL/AML.
- **Deepa Sampath, Ph.D.**, is Professor in the Department of Hematopoietic Biology and Malignancy and Professor in the Department of Leukemia, both within the Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center in Houston, TX. She currently serves as a Professor in the Department of Hematopoietic Biology and Malignancy. Dr. Sampath’s research utilizes advanced techniques such as CHIP assays, microarrays, and gene expression analyses to investigate epigenetic silencing through DNA methylation, histone modification, and polycomb repressor complexes. She contributed to the translational research of LP-118 and LP-168.
- **Wu Yilong, MD, PHD.**, Professor Wu, a globally recognized expert in lung cancer research, has received numerous prestigious honors, including the “IASLC Scientific Award,” “Wu-Yang Award,” and the “National Outstanding Professional and Technical Personnel” designation. He has been a Highly Cited Researcher in clinical medicine (2018-2019) and a recipient of awards such as the second prize of the “National Science

BUSINESS

& Technology Progress Award” and multiple first prizes for provincial and national scientific achievements. He currently serves as a Professor of Oncology at Guangdong Lung Cancer Institute, Guangdong Provincial People’s Hospital. Professor Wu has made transformative contributions to the global precision treatment of EGFR-mutated lung cancer, with his research shaping international treatment guidelines. Leading over 20 national and provincial research projects and 8 global clinical trials, he has supervised more than 80 postgraduate and doctoral students, cementing his role as a pioneer in advancing clinical oncology research in China to international prominence. In particular, Professor Wu led the early clinical development of LP-118 and served as the PI for the China Phase I study of LP-118 in patients with advanced solid tumors and lymphoma.

Our Directors are of the view that we do not significantly rely on the experience of the Science Advisory Board, considering it serves in a non-executive, advisory capacity, providing periodic strategic input on scientific direction, clinical development plans and emerging research trends. At the same time, all key decisions regarding drug candidates’ selection, trial design, resource allocation and day-to-day R&D execution are made by our core R&D staff and senior management. The number of Scientific Advisory Board members exceeds the number of core R&D personnel reflects our strategy of accessing a broad range of external, cross-disciplinary expertise rather than dependence on any individual advisor or group. Accordingly, we believe we are not materially dependent on the Scientific Advisory Board for the conduct of our business.

Drug Discovery

Our drug discovery and preclinical team is responsible for, among others, target research and mechanism validation for innovative drug development, compound molecular design and optimization, pre-clinical development, and translational science research. The pre-clinical R&D team, led by co-founder Dr. Chen, operates through four core functional modules — drug design and patent strategy, chemistry and CMC, quality systems, and biology — with particular expertise in navigating the complex challenges of bRo5 oral small molecules. Our discovery, preclinical, clinical development, and business development teams work closely together to drive our product development programs efficiently. Involving the medical team early in the R&D process allows us to identify promising programs with strong market potential and minimize the risk of unforeseen challenges during clinical development and manufacturing.

Clinical Trial Management

Our clinical trial management is led by our clinical department in both China and the United States. As of the Latest Practicable Date, our clinical R&D department comprised 52 members, including scientists and physicians with substantial experience in drug development. This team is actively involved in formulating clinical development strategies, designing clinical trial protocols, managing trial operations, monitoring drug safety, ensuring clinical trial quality control and overseeing organizational and operational management. A significant portion of our professionals of medical department possess extensive relevant expertise, with approximately 40% holding postgraduate degrees. This team primarily oversees the clinical development of our Core Product as well as other pipeline candidates.

Clinical Trial Design and Implementation

Our clinical team oversees all phases of clinical trials, from protocol design to the management and execution of trial operations. Our trial progress is driven by (i) a strategic approach to initiating clinical phases based on preclinical data, (ii) optimized trial designs supported by rigorous quantitative analysis of integrated data and comprehensive oversight throughout the process, and (iii) long-term collaborations with hospitals and principal investigators across various regions to ensure seamless trial execution.

BUSINESS

Our clinical team is also responsible for selecting trial sites. The criteria for site selection include the site’s overall experience, expertise in the relevant disease area, access to specialized experts and patient populations, geographic coverage, regulatory compliance, quality management capabilities, range of available services, staff qualifications, and technological infrastructure.

In 2024 and 2025, clinical trials were conducted in collaboration with 110 and 133 PIs, respectively. To the best of available knowledge, none of the PIs had any past or present relationships with the research group, its directors, shareholders, senior management, or their respective associates. The PIs are responsible for executing site-level clinical research activities in accordance with trial protocols, applicable laws, regulations, and the GCP guidelines, which set the quality standards for the overall conduct of clinical trials. Each trial is overseen by a lead PI who holds primary responsibility for ensuring adherence to the trial protocol and compliance with good clinical practice throughout the duration of the trial.

During the Track Record Period, we engaged one of our suppliers, Supplier C, to support the clinical trial of our Core Product by serving as a clinical trial site for its Phase I study in the United States. In addition, one of our SAB members serve as the PI in the aforementioned clinical trial. As advised by CIC, this arrangement is in line with the industry norm. The following summarizes the salient terms of the clinical trial agreement with Supplier C.

- Scope: Support a Phase I, multicenter, open-label, dose-escalation study evaluating the safety, tolerability, pharmacokinetics, and clinical activity of orally administered LP-168 in subjects with relapsed or refractory B-cell malignancies in the United States (“**Clinical Trial**”).
- Duration: Upon the conclusion of the Clinical Trial for all enrolled subjects.
- Payment: We shall pay for each enrolled subject on a monthly basis based on the clinical services provided by the trial site. The final payment will be paid once all CRFs have been completed and received.
- Responsibilities: Supplier C shall act as the trial site for the Clinical Trial and conduct the Clinical Trial in accordance with the trial protocol implemented by us.

We are responsible to provide Supplier C with sufficient quantity of LP-168 that is being studied to conduct the Clinical Trial at no cost to Supplier C.
- Termination clauses: The agreement terminates early if: (i) IRB/RA rejects Clinical Trial initiation; (ii) Clinical Trial completes with all protocol activities, data/samples, and payments settled; or (iii) early termination events occur.

During the Track Record Period, all of our drug candidates, including the Core Product, were self-developed. Our Directors confirm that, save as the aforementioned relationship, there were no other past or present relationships or arrangements (business, employment, family, trust, financing, guarantee or otherwise) between Supplier C and our Company or its subsidiaries, their controlling/substantial shareholders, directors, supervisors or senior management, or any of their respective associates.

BUSINESS

Relationship with CROs

We perform key functions internally, including the design of clinical development strategies and protocols, as well as exercising control and oversight over critical aspects of clinical trial management, such as data source validation. We engage CROs and consultants to manage, conduct, and support our clinical trials and preclinical studies across China and U.S..

The selection of CROs is based on multiple criteria, including their qualifications, academic and professional experience — particularly with global regulatory compliance — and industry reputation. These CROs provide a comprehensive range of products and services essential for the execution of complex clinical trials. Beyond the breadth, depth, and quality of their offerings, we highly value their ability to facilitate optimal site selection, timely patient recruitment, and the efficient management of intricate trials. Typically, we establish master service agreements with CROs, under which separate work orders are executed for individual preclinical or clinical research projects, or we enter into dedicated research and development contracts for specific projects. We maintain close supervision of these CROs to ensure their activities adhere to our protocols, comply with applicable laws, and uphold the integrity of the data generated from our trials and studies. Concurrently, the project or trial leader maintains regular communication with the financial departments of both the organization and the CRO, enforcing strict financial controls at various stages of the project to ensure its timely and high-quality completion. Upon conclusion of the project, a comprehensive review is conducted, and feedback is provided to improve the efficiency of future collaborations with the CRO organizations.

We closely monitor the work of our CROs and provide specific directions to ensure the quality and efficiency of the trial execution. This approach allows us to leverage the experience of our in-house team to better focus on critical clinical trial elements, such as trial design, data analysis and decision-making. All studies of our product candidates on humans are conducted in compliance with the applicable laws, regulations and in line with the industry standards. We believe our ability to conduct and work closely with CROs to conduct preclinical studies and clinical trials helps us to shorten the time required for product development as well as generate the requisite data in a reliable and efficient way.

Regulatory Affairs

Our regulatory affairs team oversees the regulatory processes for our product candidates, including preparing application dossiers for IND and NDA submissions, responding to inquiries from regulatory authorities, and monitoring our R&D projects to ensure compliance with applicable regulations. The team manages regulatory submissions across multiple key jurisdictions, such as China and the United States, where filings must be submitted and approved by the relevant authorities prior to the commencement of clinical trials and commercialization. Responsibilities of the regulatory affairs team include coordinating the drafting of filing dossiers, addressing regulatory queries, and conducting assessments of CMC and GMP readiness for our product candidates. We possess extensive expertise in regulatory filings both domestically and internationally. Leveraging our presence and experience across these jurisdictions, we design clinical trials to optimize operational efficiency and effectiveness.

CHEMISTRY, MANUFACTURING & CONTROLS

Chemistry & CMC Team

As of the Latest Practicable Date, our Chemistry & CMC team consists of 20 industry professionals — with core members averaging over 15 years of experience — dedicated to developing safe, robust, and highly efficient production processes for our active pharmaceutical ingredients (APIs) and drug products. We have established fully integrated CMC capabilities that span the entire drug development lifecycle, including early synthetic route design, dosage and formulation development, quality control validation, non- GMP kilogram-scale pilot production,

BUSINESS

and NDA-stage process validation. By proactively addressing regulatory and quality requirements during early-stage development, our team effectively prevents late-stage detours, optimizes synthetic routes, and ensures consistent manufacturing. This forward-looking strategy streamlines the transition from preclinical to clinical stages, significantly enhancing our overall R&D efficiency and cost control.

Collaboration with CDMO Partners

As of the Latest Practicable Date, we did not have beyond-lab-scale manufacturing facility. We collaborate with CDMO partners (including CMOs) to conduct and support our preclinical and clinical trials in line with industry practice. In terms of the involvement and contributions of each of the major CDMO partners (including CMOs) to the development of our drug candidates, we collaborate with our CDMO partners to manufacture certain raw materials and drug substances, such as the APIs of our drug candidates to supply for preclinical studies and clinical trials. During the Track Record Period, we have cooperated with five CDMO partners.

We did not experience any material 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 their 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 partners in accordance with market prices of similar services, the number of products manufactured, and the quality and contents of the services provided. We do not share our IPs, know-hows and trade secrets with CDMO partners.

COMMERCIALIZATION

As of the Latest Practicable Date, we did not have any commercialized product. We have submitted the NDA application to the NMPA for LP-168 for the treatment in R/R MCL in May 2025, and expect that we can receive the NDA and commence commercialization in 2026. Additionally, we have entered into a commercialization arrangement with Hansoh Pharma for the development and commercialization of LP-168 for non-oncology indications in Chinese mainland, Hong Kong, Macau and Taiwan. We will retain all research, development and manufacturing rights, as well as commercialization rights outside of the Greater China region. For details, please see “Business — Licensing Agreement.”

To lay a solid foundation for our future marketing and commercialization efforts, we plan to actively engage in academic promotions and industry seminars to familiarize market participants, such as patients, physicians and PIs of clinical trials, regarding the potential advantages of our pipeline products. We believe such efforts would also help us gain a favorable brand image and name recognition, which may contribute to maximizing the commercial value of our product portfolio. We intend to closely monitor the updates in the industry and formulate concrete commercialization plans for our pipeline programs that have entered or are approaching the NDA submission stage. We will continue to assess and select an appropriate commercialization model and may establish an in-house marketing and commercialization team or seek external collaborations, including engaging third-party contract sales organizations, if we deem it to serve our best interest.

BUSINESS

Pricing

Our pricing strategies are affected by the regulatory framework governing pharmaceutical reimbursement in China, which operates through multiple interconnected mechanisms that collectively determine both market access opportunities and pricing parameters for pharmaceutical products in China’s public healthcare system. The regulatory regimes that directly impact our pricing and market access primarily include the NRDL governing insurance coverage and reimbursement standards. We continuously monitor regulatory developments and adapt our pricing strategies to navigate these complex mechanisms while maintaining sustainable business operations.

The NRDL forms the basis for medical insurance coverage and reimbursement standards under China’s basic medical insurance, work-related injury insurance and maternity insurance programs. NRDL inclusion significantly influences market dynamics by determining patient access to insurance reimbursement for covered medications, thereby affecting both demand patterns and achievable pricing levels. The NHSA, in conjunction with other relevant government authorities, maintains authority over NRDL composition and updates the list through rigorous evaluation processes that assess clinical necessity, cost-effectiveness and budgetary impact. Products undergo comprehensive evaluation based on established selection criteria including clinical efficacy, safety profiles, therapeutic value compared to existing alternatives, and economic considerations.

NRDL inclusion represents both an opportunity for enhanced market access and a commitment to pricing frameworks that support broad patient accessibility within China’s healthcare insurance system. While NRDL inclusion provides substantial market advantages through enhanced patient accessibility and reduced out-of-pocket costs, it may also result in price adjustments through negotiated pricing mechanisms designed to balance patient access with healthcare system sustainability. As of the Latest Practicable Date, we have been making steady progress in advancing the inclusion of our Core Product in the NRDL. In particular, we had already started to work with the KOLs to prepare for the NRDL negotiation, with an aim to include LP-168 in the NRDL in the first year following its NDA approval. Considering the potential clinical advantages of LP-168 as a “covalent and non-covalent” BTK inhibitor, we believe it may be favorably positioned for potential inclusion in the NRDL. However, we cannot guarantee that it will be included, as the final determination is subject to complex pricing negotiations and government policies that are ultimately beyond our control. For details, please see “Regulatory Overview — Regulations on Coverage and Reimbursement in the PRC” and “Risk Factors — Risks Relating to Our Business and Industry — If our products fail to be timely included in, or are removed or excluded from, national, provincial or other government-sponsored medical insurance programs, our revenue and financial performance could be adversely affected.”

Save as disclosed above, there are no other regulatory regimes that may directly and materially impact the pricing and market access of our products.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we held a total of 71 patents and patent applications in relation to the technology solutions of our Core Product, comprising 55 granted patents and 16 filed patent applications. Among the 55 granted patents, three were granted in the PRC, seven in the United States and 45 in other countries or regions. We believe these patent covered the material aspects of our Core Products. Among the 16 filed patent applications, two were filed in the PRC, three in the United States and 11 in other countries or regions. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that makes us to believe that any of the pending patent applications will be rejected.

BUSINESS

Registered Patents

As of the Latest Practicable Date, we owned the following registered patents which we consider to be or may be material to our business, all of which were derived from our BeyondX Oral MedChem Platform:

Relevant Product	Patent	Type of patent	Place of registration	Patent number	Owner	Expiration date
LP-168	Substituted pyrazines as inhibitors of BTK, and mutants thereof	Invention	U.S.	US11501284	Newave	May 27, 2039
LP-168	Substituted pyrazines as inhibitors of BTK, and mutants thereof	Invention	U.S.	US12086788	Newave	February 15, 2039
LP-168	Inhibitors of btk and mutants thereof	Invention	PRC	ZL201980013997.5	Guangzhou Lupeng	February 15, 2039
LP-168	BTKおよびその変異体の阻害剤	Invention	Japan	JP7535949	Guangzhou Lupeng	February 15, 2039
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	U.S.	US11365206	Newave	October 13, 2038
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	U.S.	US11993610	Newave	August 22, 2038
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	PRC	ZL201880067225.5	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Bcl-2阻害剤	Invention	Japan	JP7467331	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	France	EP3672976(FR)	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	UK	EP3672976(GB)	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	Netherlands	EP3672976(NL)	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	Switzerland	EP3672976(CH)	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Condensed heterocyclic derivatives as Bcl-2 inhibitors for the treatment of neoplastic diseases	Invention	U.S.	US11279711	Newave	October 19, 2038
LP-108 and LP-118 . . .	Condensed heterocyclic derivatives as Bcl-2 inhibitors for the treatment of neoplastic diseases	Invention	U.S.	US11680072	Newave	August 22, 2038

BUSINESS

Relevant Product	Patent	Type of patent	Place of registration	Patent number	Owner	Expiration date
LP-108 and LP-118 . . .	Condensed heterocyclic derivatives as Bcl-2 inhibitors for the treatment of neoplastic diseases	Invention	PRC	ZL201880067185.4	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Condensed heterocyclic derivatives as Bcl-2 inhibitors for the treatment of neoplastic diseases	Invention	Hong Kong	HK40033360	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	新生物疾患の治療のためのBcl-2阻害剤としての縮合複素環式誘導體	Invention	Japan	JP7467332	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Condensed heterocyclic derivatives as Bcl-2 inhibitors for the treatment of neoplastic diseases	Invention	UK	EP3672975 (GB)	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Condensed heterocyclic derivatives as Bcl-2 inhibitors for the treatment of neoplastic diseases	Invention	France	EP3672975 (FR)	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Condensed heterocyclic derivatives as Bcl-2 inhibitors for the treatment of neoplastic diseases	Invention	Switzerland	EP3672975 (CH)	Guangzhou Lupeng	August 22, 2038
LP-108 and LP-118 . . .	Hot melt extruded solid dispersions containing a Bcl-2 inhibitor	Invention	PRC	ZL202180016511.0	Guangzhou Lupeng	February 23, 2041
LP-108 and LP-118 . . .	Bcl2阻害剤を含むホットメルト押出し固體分散體	Invention	Japan	JP7849296	Guangzhou Lupeng	February 23, 2041

BUSINESS

Patents under Application

As of the Latest Practicable Date, we have applied for the registration of the following patents which we consider to be or may be material to our business. Based on public search results and as advised by the legal experts we engaged for the application of these patents, we do not foresee any material legal or practical impediments to complete the registration of the relevant patents:

Relevant Product	Patent Application	Type of Patent	Place of Registration	Patent Application Number	Applicant	Application Date
LP-168	Inhibitors of BTK and mutants thereof	Invention	Canada	CA3088796	Guangzhou Lupeng	February 15, 2019
LP-168	Inhibitors of btk and mutants thereof	Invention	Europe	EP19709178.8	Guangzhou Lupeng	February 15, 2019
LP-168	Inhibitors of BTK and mutants thereof	Invention	Hong Kong	HK62021027574.4	Guangzhou Lupeng	March 18, 2021
LP-168	Dosage form compositions comprising an inhibitor of BTK and mutants thereof	Invention	U.S.	US18/020980	Newave	August 13, 2021
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	Canada	CA3073446	Guangzhou Lupeng	August 22, 2018
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	PRC	CN202310439771.X	Guangzhou Lupeng	August 22, 2018
LP-108 and LP-118 . . .	Bcl-2 inhibitors	Invention	Canada	CA3073445	Guangzhou Lupeng	August 22, 2018
LP-108 and LP-118 . . .	Hot melt extruded solid dispersions containing a Bcl-2 inhibitor	Invention	U.S.	US17/798904	Newave	February 23, 2021
LP-108 and LP-118 . . .	Hot melt extruded solid dispersions containing a Bcl-2 inhibitor	Invention	Canada	CA3173041	Guangzhou Lupeng	February 23, 2021
LP-108 and LP-118 . . .	Hot melt extruded solid dispersions containing a Bcl-2 inhibitor	Invention	Europe	EP21712350.4	Guangzhou Lupeng	February 23, 2021

Notes:

- (1) Unless otherwise indicated, the patent for applications within the same family is the same and is therefore disclosed once.
- (2) The patent expiration date is estimated based on current filing status, without considering any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our drug candidates. We seek to protect our proprietary drug candidates and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we used to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

BUSINESS

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. For details on risks associated with our intellectual properties, please see “Risk Factors — Risks Relating to Our Intellectual Property Rights.”

We conduct our business under the brand name of “LUPENG PHARMACEUTICAL” or “麓鵬製藥.” As of the Latest Practicable Date, we held 106 registered trademarks in Chinese Mainland. We are also the owner of eight domain names.

During the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any legal, arbitral or administrative proceedings in respect of, and we had not received notice of any material claims of infringement, misappropriation or other violations of, third-party intellectual property; and (ii) we were not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the research and development for any of our drug candidates in which we may be a claimant or a respondent.

OUR SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of CROs, principal investigators and other clinical-related service providers. We engage CROs and consultants to manage, conduct, and support our clinical trials and preclinical studies across China and U.S.. In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. For details, see “— Research and Development — Clinical Trial Management — Relationship with CROs” and “— Chemistry, Manufacturing & Controls — Collaboration with CDMO Partners”

In 2024 and 2025, our purchases from our five largest suppliers in each period in aggregate amounted to RMB42.4 million and RMB30.5 million, representing 44.1% and 36.1% of our total corresponding purchases in each period during the Track Record Period, respectively. In the same period, our purchases from the largest supplier amounted to RMB28.2 million and RMB15.7 million, representing 29.3% and 18.5% of our total corresponding purchases in each period during the Track Record Period, respectively.

The following table sets forth details of our five largest suppliers during the Track Record Period.

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount <i>(RMB in thousand)</i>	% of Total Purchases for the Period/Year <i>(%)</i>
<i>For the year ended December 31, 2025</i>						
Supplier A . . .	A leading China-based CRO with global presence with a registered capital over RMB2,500 million, and a HK-listed company	CRO services	30 days	2018	15,664	18.5%
Supplier B . . .	A U.S.-based CRO company specializing in biometrical and clinical science services	Data management and statistical analysis services	Milestone payments	2019	5,921	7.0%

BUSINESS

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount <i>(RMB in thousand)</i>	% of Total Purchases for the Period/Year <i>(%)</i>
Supplier C . . .	A major U.S. public research university office supporting sponsored projects and research collaborations and served as a trial site for the Phase I clinical trial of LP- 168	R&D services	30 days	2021	3,025	3.6%
Supplier D . . .	A long-established US law firm offering full-service legal counsel across corporate and litigation fields and among the largest law firms in the U.S., who is responsible for our patent application and patent portfolio maintenance	Consulting services	15 days	2015	3,022	3.6%
Supplier E . . .	A China-based medical technology company focusing on innovative healthcare solutions with a registered capital over RMB250 million	SMO services	45-60 days	2021	2,855	3.4%
Total					30,487	36.1%

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount <i>(RMB in thousand)</i>	% of Total Purchases for the Period/Year <i>(%)</i>
<i>For the year ended December 31, 2024</i>						
Supplier A . . .	A leading China-based CRO with global presence with a registered capital over RMB2,500 million, and a HK-listed company	CRO services	30 days	2018	28,152.0	29.3
Supplier E . . .	A China-based medical technology company focusing on innovative healthcare solutions with a registered capital over RMB250 million	SMO services	45-60 days	2021	4,069.0	4.2

BUSINESS

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount (RMB in thousand)	% of Total Purchases for the Period/Year (%)
Supplier C . . .	A major U.S. public research university office supporting sponsored projects and research collaborations and served as a trial site for the Phase I clinical trial of LP-168	R&D services	30 days	2021	3,612.0	3.8
Supplier F . . .	A U.S.-based physician group providing comprehensive clinical and academic healthcare services with 21 departments specialized in different clinical and academic domains	R&D services	50 days	2021	3,550.0	3.7
Supplier G . . .	A leading cancer hospital in China specializing in oncology treatment, research, and education with more than 3,500 employees	R&D services	Prepayment	2022	3,022.0	3.1
Total					42,405.0	44.1

None of our Directors, their respective close associates or any Shareholders who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, had any interest in any of our five largest suppliers for each year/period during the Track Record Period.

OUR CUSTOMER

During the Track Record Period, we had received revenue from our customer, primarily representing upfront fees and technology transfer milestone payment related to the LP-168 License Agreement. In 2024 and 2025, our revenue generated from this customer amounted to nil and RMB32.1 million, respectively.

To the best of our knowledge, our customer during the Track Record Period is an Independent Third Party. 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 such customer during the Track Record Period.

COMPETITION

The biopharmaceutical industries are defined by fast-evolving technologies, intense competition, and a significant focus on proprietary drug development. Although our diversified pipeline of clinical and preclinical drug assets, advanced R&D expertise, innovative technology platforms, and experienced management team give us a competitive advantage, we encounter

BUSINESS

competition from diverse sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any drug candidates we bring to market will compete against both existing drugs and emerging drugs.

See “Industry Overview” for a detailed analysis of the competitive dynamics in our target markets. Additionally, clinical trial progress is subject to numerous uncertainties, including achieving encouraging safety and efficacy outcomes, successful patient recruitment, and the effective performance of CROs and other clinical development partners.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies include coverage for adverse events arising from clinical trials and commercial insurance for certain employees. We currently do not maintain insurance for environmental liability or property loss. Please refer to “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.”

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 152 employees in total, and 64 employees were stationed in our headquarters in Guangzhou, Guangdong Province. As of the same date, seven employees were based overseas and were primarily responsible for clinical development and administrative affair. During the Track Record Period and up to the Latest Practicable Date, we had made sufficient contributions directly or indirectly to social insurance and housing provident funds for our employees in accordance with applicable PRC laws and regulations. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Functions	Number of employees by function
Management and administrative	27
Non-clinical R&D	27
Clinical R&D	52
Sales and marketing	46
Total	152

We establish individual employment agreements with our employees, outlining terms related to salaries, bonuses, benefits, workplace safety, confidentiality, non-compete obligations and conditions for termination.

To maintain our workforce’s quality, knowledge, and skill levels, we invest in ongoing professional development through internal and external training programs designed to enhance technical, managerial, and policy compliance competencies. Additionally, we offer competitive remuneration packages — including performance-based bonuses and equity incentives — to attract and retain talent, particularly key personnel.

As of the Latest Practicable Date, we did not have an established labor union. We believe that we maintain good working relationships with our employees and had not encountered any material labor disputes or recruitment challenges during the Track Record Period. Our employees’

BUSINESS

remuneration comprises base salaries, allowances (such as transportation, meal, communication, high-temperature and nutrition subsidies), bonuses (including project bonuses and year-end bonuses), provident funds, mandatory social security contributions (covering pensions, medical, unemployment, work-related injury, and maternity insurance), and housing funds, pursuant to applicable laws and regulations. We have complied with all statutory social security insurance fund and housing fund obligations applicable to us under the laws and regulations in China in all material aspects during the Track Record Period and as of the Latest Practicable Date.

PROPERTIES

As of the Latest Practicable Date, we did not own any real property. As of the same date, we leased 13 properties, primarily as our offices and R&D facilities, all located in mainland China, with an aggregate GFA of approximately 3,954.78 square meters. 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.

According to applicable PRC administrative regulations, both the lessor and the lessee of a lease agreement are required to file the lease agreement with the relevant government authorities within 30 days of its execution. Currently, six of our lease agreements were not registered. As advised by our PRC Legal Advisor, the absence of registration will not affect the validity of the lease agreements, nor materially and adversely affect the operations of our Company and Major Subsidiaries, but we may be subject to a fine of RMB1,000 to RMB10,000 for each unregistered lease agreement if we and the landlord fail to register such lease agreements as required by the relevant competent authorities. As advised by our PRC Legal Advisors, we believe that the non-registrations of leases described above will not, individually or in the aggregate, materially affect our business and results of operations. See “Risk Factors — Risks Relating to Our Operations — Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them.”

As of the Latest Practicable Date, no single property interest that formed part of non-property activities had a carrying amount of 15%, and no single property interest that formed part of property activities had a carrying amount of 1%, of our total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to our Group’s interests in land or buildings.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

We believe that our continued growth depends on the integration of social values into our business strategy. We are committed to delivering reliable treatments and therapies that not only improve patient outcomes but also contribute to a healthier, more sustainable world. We recognize that corporate social responsibility is not only a fundamental obligation but also a key driver of long-term success. Accordingly, we have embedded environmental, social, and governance (“ESG”) considerations into our corporate governance framework and day-to-day operations. We will comply with the ESG reporting requirements after the [REDACTED] and the responsibility to publish ESG report on an annual basis in accordance with Appendix C2 to the Listing Rules. We will focus on each of the areas as specified in Appendix C2 to the Listing Rules to analyze and disclose important ESG matters, risk management and the accomplishment of performance objectives, particularly those environmental and social issues that could have a material impact on the sustainability of our operations and that are of interest to our Shareholders.

BUSINESS

ESG Governance

We have implemented a strong ESG governance framework to guide our efforts in environmental sustainability, social responsibility, and corporate governance. We are committed to strengthening our ESG oversight mechanisms by thoroughly integrating environmental, social, and governance factors into our business operations and ensuring compliance with relevant environmental protection laws and regulations. By proactively assessing ESG-related risks and opportunities — including through environmental impact evaluations — we aim to develop effective mitigation strategies while optimizing cost-efficiency and sustainable growth. Our emissions reduction goals are based on industry standards and our operational circumstances, ensuring measurable progress toward environmental excellence. A structured, phased timeline will be established to track and achieve these ESG objectives systematically. Additionally, we are committed to fostering a culture of compliance, with a goal to ensure that all employees are well-informed of and adhere to relevant ESG regulations and requirements through cross-departmental collaboration.

We have developed ESG management policies and established a three-tier ESG governance structure, which includes the Board of Directors, our ESG Committee, and the ESG Working Team, to effectively manage ESG issues.

Our Board serves as the ultimate authority, bearing comprehensive responsibility for our ESG strategy and reporting. Its key responsibilities are as follows:

- The Board bears ultimate responsibility for our ESG strategy, risk management, disclosures and alignment with overall corporate objectives.
- The Board reviews and approves ESG strategic plans, annual targets, budgets, and the compliance, adequacy and quality of ESG reports.
- The Board oversees the effectiveness of the ESG risk management framework and ensures timely disclosure of material ESG incidents, including environmental accidents and clinical trial violations.

Our ESG Committee comprises department heads, including the heads of finance, research and development, and procurement, with expertise in ESG data collection, performance tracking and reporting. The CFO and key personnel are responsible for ESG implementation. Their key responsibilities include:

- Collecting ESG performance data and reviewing ESG reports.
- Continuously monitoring our ESG strategies, policies, guidelines, and procedures, and ensuring the effectiveness of ESG risk management and internal control systems.
- Facilitating cross-departmental ESG communication and coordination.

The ESG Working Team, comprising various functional departments and operating under the management’s oversight and guidance, is responsible for:

- Drafting and implementing ESG policies and initiatives, as well as drafting response measures for any challenges or risks that may affect the achievement of ESG objectives.
- Preparing the annual ESG report, including the collection, analysis, evaluation, and documentation of ESG data and information.
- Reporting to our ESG Committee regularly, including but not limited to the implementation status of the ESG work plan and report, ESG risks and opportunities, and regulatory trends and market developments related to ESG matters.
- Organizing ESG-related training and awareness programs.

BUSINESS

Environmental Protection

As a biopharmaceutical company, we recognize the significant environmental responsibilities that come with our operations. Environmental responsibility is deeply ingrained in our corporate values, guiding our efforts to reduce ecological harm at every stage of the value chain. We are focused on ongoing improvement, striving to lower our environmental footprint while advancing sustainable growth in alignment with our commitment to planetary stewardship.

Climate Change

We recognize that climate-related risks and opportunities have a direct influence on our industry, making climate action a key strategic focus. Our proactive strategy involves implementing a comprehensive ESG governance framework to identify, monitor, and address climate risks across all aspects of our operations. We are actively enhancing energy efficiency, reducing greenhouse gas emissions, and improving our overall environmental performance. At the same time, we are capitalizing on climate-related opportunities by driving innovation that supports both sustainability and sustained business growth.

Governance

We will integrate climate change governance within our broader ESG framework upon [REDACTED]. Supported by cross-functional teams, our Board and senior management actively identify and assess climate-related risks and opportunities. They directly oversee greenhouse gas emissions monitoring and drive energy conservation and emissions reduction initiatives.

Strategy and Risk Assessment

Our climate-related risks primarily fall into two categories: physical risks arising from extreme weather events, and transition risks associated with the global shift toward a low-carbon economy.

- Physical risks include disruptions caused by extreme weather events such as heavy rainfall and flooding, which may result in power outages, water supply interruptions, and damage to equipment and facilities. Such events can affect the continuity of our research and development activities and other core operations, while also posing risks to employee safety. To mitigate these risks, we have established comprehensive emergency response plans, conduct regular safety training to raise employee awareness, and are enhancing the climate resilience of our facilities through measures such as improved flood protection.
- Transition risks stem from increasingly stringent regulatory requirements related to climate disclosures and carbon emissions. National and local authorities continue to introduce policies aimed at limiting greenhouse gas emissions, which may impose additional compliance obligations on our operations. In addition, climate change may contribute to rising costs for raw materials and energy used in pharmaceutical production. In response, we actively monitor relevant climate-related laws and regulations, strengthen the tracking and supervision of greenhouse gas emissions, and promote energy efficiency, consumption reduction, and green office practices throughout our daily operations.

BUSINESS

Metrics and Targets

We are committed to energy conservation and reducing our carbon footprint. To fulfil our responsibility’s, we target to achieve a 5.0% decrease in electricity consumption in 2025 compared to the levels in 2024, which will lead to a decrease in our greenhouse gas emission. The following table sets forth the amount of our greenhouse gas emissions for the periods indicated:

	Unit	For the year ended December 31,	
		2024	2025
Greenhouse gas emissions . . .	tons of CO2 equivalent	149.1	159.1
– Scope 1 (direct emissions)	tons of CO2 equivalent	–	–
– Scope 2 (indirect emissions)	tons of CO2 equivalent	149.1	159.1

Notes:

- (1) During the Track Record Period, there was no Scope 1 emissions from sources that were owned or controlled by us. Therefore, there were no available Scope 1 emissions in the Track Record Period.
- (2) Figures relating to Scope 2 GHG emissions are mainly derived from electricity consumption and heating related to operations. Electricity emissions are calculated based on the national average carbon dioxide emission factor for electricity published by the Ministry of Ecology and Environment, the PRC.
- (3) We are currently formulating a Scope 3 carbon inventory plan. With the further improvement of relevant upstream and downstream basic data and emission factors, we will proceed to conduct the Scope 3 inventory.

Environmental Impact Management

We implement comprehensive policies to minimize our environmental impact through responsible waste management, energy efficiency, and water conservation.

For waste handling, we strictly comply with environmental regulations by properly sorting and disposing of domestic non-hazardous waste through licensed providers, while qualified third parties manage all hazardous materials from R&D through rigorous procedures to ensure safety and compliance; hazardous materials generated from clinical trials are handled by the respective hospitals.

Our energy conservation efforts include upgrading to efficient equipment, optimizing heating, ventilation and air conditioning and lighting systems, and training employees in sustainable practices. Simultaneously, we reduce water usage through process improvements, leak prevention systems, and water-saving installations across our facilities. These integrated measures demonstrate our proactive approach to environmental stewardship. In 2026, as we continue business expansion, we target to achieve a 1% decrease in electricity consumption compared to the levels in 2024 through our ongoing commitment to environmental protection.

During the Track Record Period, our waste emissions and resource usage are primarily resulted from our R&D activities in Guangzhou and Suzhou. The following table sets forth our waste emissions and resource usage in these premises for the year/period indicated:

	Unit	For the year ended December 31,	
		2024	2025
Hazardous Waste	tons	10.5	8.4
Non-hazardous Waste	tons	2.6	2.8
Electricity Consumption	MWh	344.7	367.8
Water Consumption	cubic meters	302	424

BUSINESS

Social Responsibility

As a responsible corporate citizen, we are committed to consistently fulfilling our corporate social responsibilities. Guided by a people-centered philosophy, we strive to create sustainable value for all stakeholders through inclusive and responsible business practices. We foster a workplace culture built on equality, respect, and inclusivity, empowering every employee to grow and contribute meaningfully. We place strong emphasis on employee health and well-being, recognizing them as key to long-term success. At the same time, we are dedicated to strengthening our quality control systems to ensure that our products meet the highest standards, while upholding ethical principles throughout our research and development processes.

Workplace Safety and Diversity

We have established and maintain a comprehensive set of rules, standard operating procedures, and measures, to ensure a healthy, safe, and inclusive environment for our employees. Our safety program emphasizes three core pillars: implementing clear guidelines for safe workplace practices, maintaining rigorous accident prevention protocols, and establishing transparent reporting procedures. For clinical trials, we require participants to demonstrate their understanding of all safety considerations both during initial enrollment and throughout their continued participation. These systematic protections reflect our fundamental commitment to fostering both physical safety and psychological well-being across all aspects of our operations.

We have also adopted a board diversity policy which sets out the approach to achieve diversity of the Board. We recognize and embrace the benefits of having a diverse Board, including gender diversity, as an essential element in maintaining our competitive advantage and enhancing our ability to attract, retain and motivate employees from the widest possible pool of available talent. As of the Latest Practicable Date, 91 of our total employees were female. After the [REDACTED], we will continue to take steps to promote gender diversity at the Board and management level. Specifically, we will actively identify female individuals suitably qualified to become our Board members. To further ensure gender diversity in a long run, our Nomination Committee will periodically review our board diversity policy and its implementation to ensure its implementation and monitor its continued effectiveness.

Employee Health and Safety

Employee health and safety remains our foremost operational priority. We maintain full compliance with all occupational health and safety regulations across every jurisdiction where we operate. Through continuous improvement of our safety management systems, we ensure operational stability while protecting our workforce. Our proactive approach includes regular workplace inspections and comprehensive risk assessments to identify potential hazards before they materialize. When risks are detected, we implement immediate corrective measures to preserve safe working conditions. We reinforce this physical protection with mandatory safety training programs that keep employees informed about relevant regulations and company protocols. During the Track Record Period, we did not experience any material health or workplace safety incidents, either in operational or administrative settings.

Supply Chain Management

Our supply chain network comprises CROs, CDMOs, and suppliers of raw materials and equipment. We strategically select partners based on five critical criteria: technical capability, cost-effectiveness, delivery performance, market reputation, and regulatory compliance. Accordingly, we define risks related to supply chains consisting of shortage of raw materials, workforce health and safety incidents, proper disposal of hazardous waste, and internal control for corruption and bribery. To identify and cope with any potential risks, we established procurement management policies that clearly define the overall review and evaluation processes for suppliers.

BUSINESS

In addition, we tend to opt for scaled suppliers with good reputation as we believe such partners are subject to stricter compliance standards and capable of offering more environmentally friendly products and services. We have also implemented strict anti-corruption and anti-bribery policies to prevent collusion and corruption.

Pre-clinical and Clinical Study

We have established comprehensive safety protocols and compliance measures to ensure the highest standards of laboratory operations and clinical trial management. Our approach includes implementing and strictly enforcing internal policies on clinical trial safety that are regularly reviewed and updated to reflect evolving regulations. We further strengthen our safety framework by requiring all contracted CROs to undertake to comply with all confidentiality obligations under our agreements and to strictly adhere to GCP requirements in the conduct of clinical trials as a condition of collaboration. These multilayered measures demonstrate our unwavering commitment to maintaining regulatory compliance while safeguarding participant well-being and data security throughout our research activities.

In addition to clinical trial quality, ethics is also an essential part of pharmaceutical R&D management framework. We strictly comply with laws, regulations, and ethical standards such as the Declaration of Helsinki of the World Medical Association and the Regulations for the Administration of Laboratory Animals. Our aim is to protect the legitimate rights and interests of human subjects and ensure the welfare of laboratory animals. We comprehensively safeguard the rights of clinical trial subjects, including their right to be informed, the right to privacy, and drug-use safety.

All clinical trials are carried out in compliance with regulations based on the informed consent of the subjects. Meanwhile, we fully consider the interests of laboratory animals in our experiments. We have established the Standard Operating Procedures for the Ethical Review of Laboratory Animal Welfare, to ensure that laboratory animals enjoy basic rights during their lives, including transportation. They should have a living environment free from hunger, thirst, and discomfort. The management of all types of laboratory animals must conform to corresponding operation technical procedures.

Corporate Governance

We uphold rigorous corporate governance standards as the foundation of our sustainable growth and long-term success. Our governance framework is structured to ensure robust oversight, transparency in decision-making, and value creation for all stakeholders. The Board of Directors serves as the guiding force in shaping our strategic direction, overseeing comprehensive risk management, and maintaining accountability throughout the organization.

ESG-Related Risks Management

We place a high priority on the identification, assessment, and management of ESG-related risks. We have established a systematic risk management framework to evaluate the potential impact of ESG issues on our business operations and financial performance and to formulate corresponding mitigation measure. We recognize that climate change poses both risks and opportunities to our business. Our operations and those of our key suppliers in the value chain could be susceptible to the following climate-related risks:

- Transition risks stem from the shift to a low-carbon economy, involving significant policy, legal, technological, and market changes. These include compliance risks from stricter environmental regulations and market risks from shifting consumer preferences towards eco-friendly products. Failure to adapt our products and operations could negatively impact our competitiveness.

BUSINESS

- Physical risks mainly include increase costs associated with, the storage and transportation of our pharmaceutical products. Disasters created by extreme weather conditions may damage our facilities, leading to additional repair or replacement costs or resulting in temporary or long-term disclosure. They may also disrupt logistics or cause delivery delays, which, in turn, may expose us to additional costs associated with third-party liabilities.
- Opportunities: We may need to further invest in the development of green pharmaceutical products, characterized by sustainable sourcing and biodegradable packaging. We may also need to further invest in environmental and energy-saving initiatives. Any failure to address the growing market demand for eco-friendly products may affect our business, competition and damage our reputation.

We face social risks primarily related to our supply chain and workforce. Risks in our supply chain could arise from the failure of our suppliers to comply with applicable laws and our standards concerning environmental protection, labor rights, and health and safety. Our risk identification and management process involves the following key steps:

- Risk Identification. We identify and analyze potential risks from internal and external sources by taking into account our development strategy, the characteristics of the industry, and the macroeconomic environment.
- Risk Assessment. We assess the identified risks based on their nature, likelihood of occurrence, and the potential severity of their impact on our operations and strategy.
- Risk Response. Based on the assessment results, we formulate and implement targeted risk mitigation measures, which include continuously monitoring risks, updating our response plans, allocating necessary resources to ensure business continuity, and conducting relevant compliance training to enhance the risk management awareness of our employees. We have also established emergency response procedures to ensure that effective measures can be taken promptly in the event of an incident.

Internal Control

We maintain rigorous internal controls and whistleblower protections to proactively identify and address misconduct, including fraud, corruption, and conflicts of interest. Our comprehensive ethics program includes mandatory employee training and clear communication protocols to ensure organization-wide understanding of compliance obligations and risk management responsibilities. For details, see “— Risk Management and Internal Control.”

Regulatory Compliance

We operate in an increasingly stringent regulatory environment for environmental, health and safety standards. In response, we have established a strong culture of compliance that is embedded throughout our organization. We require strict adherence not only to legal requirements but also to industry standards and ethical principles, which we reinforce through comprehensive training programs, clearly documented policies, and consistent leadership communication.

We believe that our operations maintain substantial compliance with all applicable regulations as currently interpreted. During the Track Record Period through the Latest Practicable Date, we have preserved an exemplary compliance record with no material fines, significant accidents, or substantial claims that would adversely impact our financial condition or business operations. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we had complied with all PRC laws and regulations applicable to us in all material respects. This clean record reflects our fundamental commitment to operational integrity and responsible business practices.

BUSINESS

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations and such licenses, permits and certifications all remain in full effect. Our PRC Legal Advisor has advised that, during the Track Record Period and up to the Latest Practicable Date, we had obtained all major licenses, permits, and certificate which are necessary to conduct our operations in all material respects from the relevant government authorities in China. For more details regarding the laws and regulations to which we are subject, see “Regulatory Overview” in this document. We currently do not expect to have any material difficulty in renewing them when they expire, if applicable.

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

License/Permit	Issuing Authority	Holder	Grant Date	Expiration Date
Pharmaceutical Production Permit (License No.: Guangdong 20250009)	Guangdong Drug Administration	Guangzhou Lupeng	April 28, 2025	April 27, 2030
Clinical Trial Approval Notice for Drug (Notice No.: 2021LP00318)	National Medical Products Administration	Guangzhou Lupeng	March 11, 2021	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2021LP01839)	National Medical Products Administration	Guangzhou Lupeng	November 11, 2021	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2023LP01249)	National Medical Products Administration	Guangzhou Lupeng	June 30, 2023	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2023LP01612)	National Medical Products Administration	Guangzhou Lupeng	August 17, 2023	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2024LP02458)	National Medical Products Administration	Guangzhou Lupeng	October 29, 2024	N/A
Clinical Trial Notification (Notification No.: CXHL1900383).	National Medical Products Administration	Guangzhou Lupeng	February 13, 2020	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2020LP00179)	National Medical Products Administration	Guangzhou Lupeng	August 10, 2020	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2022LP01695)	National Medical Products Administration	Guangzhou Lupeng	October 14, 2022	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2021LP00668)	National Medical Products Administration	Guangzhou Lupeng	May 10, 2021	N/A
Clinical Trial Approval Notice for Drug (Notice No.: 2021LP01362)	National Medical Products Administration	Guangzhou Lupeng	August 30, 2021	N/A

BUSINESS

LEGAL PROCEEDINGS AND NON-COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we have not been involved in any material legal or administrative proceedings that could significantly impact our operations, financial position, growth prospects, or reputation. While we maintain this clean litigation record, like all companies in our industry, we may occasionally face routine claims or proceedings arising from normal business activities. For details, see “Risk Factor — We, our management, and directors may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.”

Legal Compliance

We maintain compliance with all applicable laws and regulations governing our operations. During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation.

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. 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 C1 to the Listing Rules.

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

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

BUSINESS

We have also appointed external legal counsel to advise us on compliance matters, such as compliance with the regulatory requirements on clinical R&D, which is also monitored by our legal compliance 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 laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

Anti-bribery

We uphold stringent anti-corruption standards and a clear code of conduct for all employees and distributors. Our policies explicitly forbid bribery, kickbacks, inappropriate gifts, or any form of improper payment — whether involving government officials, healthcare professionals, or private entities — in every market where we operate. We require meticulous financial record-keeping and prohibit falsified documents, misleading entries, or unusual payments, with mandatory reporting of any suspicious requests.

As part of our compliance framework, we will ensure that future commercialization teams strictly follow promotional regulations, including bans on off-label marketing and ethical guidelines for sponsored educational activities. Our proactive approach positions us to adapt effectively to China’s evolving anti-corruption landscape while maintaining global integrity.

We have implemented a robust internal control system to prevent corruption and bribery through: (i) conducting regular compliance training for all employees and senior management, including daily team briefings, annual certification programs, and specialized sessions, to ensure thorough understanding of legal requirements; (ii) maintaining rigorous financial oversight, with particular attention to supplier contracts, tender processes, and payment systems, to detect and prevent any irregular or undisclosed transactions; and (iii) establishing confidential whistleblowing channels that empower employees, business partners, and third parties to safely report policy violations or suspicious behavior. Together, these measures create multiple layers of protection while fostering a culture of integrity and accountability across our organization.

Conflict of Interest and Non-Competition

Our code of conduct strictly prohibits conflicts of interest across all business relationships, including with suppliers, customers, and competitors. All employees, including but not limited to our Directors and R&D team members, must avoid: (i) holding personal financial interests in dealings with business partners or competitors; (ii) accepting improper benefits from third parties; (iii) having close relatives employed at partner or competitor organizations; or (iv) serving in advisory/director roles at competing enterprises. Employees must rigorously protect confidential information, including trade secrets and proprietary technologies.

Our employment contracts contain enforceable — two year non-compete clauses preventing former staff from engaging in similar businesses post-employment, and current employees require written approval for any involvement with competing entities. These measures collectively ensure ethical operations while safeguarding our intellectual property and competitive interests.

BUSINESS

Data Privacy Protection

In the course of our clinical development, collaborations, and operations, the personal data we process includes the names, contact information, resumes, and other details of clinical trial project team members (including our own employees, as well as Project Managers and CRCs dispatched by SMOs we collaborate with, clinical trial site investigators and their research teams). It also includes subjects’ demographic information such as subject identification codes, dates of birth, age, ethnicity, as well as personal health and physiological information like medical history and laboratory reports. These data are strictly necessary for the conduct of the relevant clinical trial projects. The personal data of project team members is primarily provided to us by our partners, such as SMOs and clinical trial institutions. Subject personal data is collected by the clinical trial site research teams and shared with us. Every subject is required to sign an informed consent form prior to enrollment in the clinical trial. In addition, our agreements with clinical trial partners require that the provision of personal information regarding clinical trial project team members be supported by authorized consent or other legal bases. Ownership of the personal information remains with the respective individuals.

We have implemented comprehensive data protection measures to safeguard subject confidentiality and ensure compliance with applicable data privacy regulations. Our strict internal policies, including but not limited to the Data Classification and Grading Management System, the Data Security Management System, and the Personal Information Protection System, govern the entire data lifecycle, from collection and storage to access and retrieval. We employ multi-layered IT security measures, including Huawei Cloud firewall and encryption technologies, to protect our internal information systems and data against unauthorized access, with designated database administrators overseeing daily maintenance, access controls, and security protocols. Furthermore, we utilize third-party information systems compliant with GCP requirements, for the collection and storage of drug clinical trial data. In accordance with GCP requirements, we restrict clinical trial data access to authorized personnel only and mandate confidentiality agreements for all employees and external partners involved in research activities. Subject data may only be used for purposes explicitly authorized in the informed consent forms. All personnel are required to handle clinical trial data in compliance with GCP requirements.

We protect clinical trial participant data through legally compliant protocols that bind both external partners and internal personnel. We contractually require CROs to: (i) maintain strict confidentiality of all trial-related information; (ii) enforce identical confidentiality obligations on their personnel; and (iii) without our prior written consent, CROs are generally prohibited from using confidential information for any purposes beyond the scope of the contract in any form. To ensure data security, we have established data security management systems and operational procedures covering personnel management and training, data security technical measures, identity management and access control, risk early warning and handling, as well as information security incident prevention and response. This forms a comprehensive internal management system that covers the entire data lifecycle. Specifically, regarding cross-border data transfer management, clinical trial data generated within China is stored on domestic servers. If it is necessary to transfer subject personal data abroad, such as in pharmacovigilance scenarios, we will conduct a prior internal self-assessment to ensure that cross-border data transfers are compliant and risks are controllable, and we will comply with the relevant data export procedures stipulated by the laws and regulations in the PRC.

Additionally, we require all employees with access to sensitive information to sign comprehensive confidentiality agreements. These agreements legally bind staff to: (i) protect confidential data during employment; (ii) return all sensitive materials upon resignation; and (iii) maintain confidentiality even after leaving the company. To reinforce these obligations, we implement robust compliance measures including mandatory data security training that educates employees on proper information handling protocols and policy requirements.

BUSINESS

During the Track Record Period and up to the latest practicable date, we have not experienced any incidents of patient data or other personal data breaches or significant losses. During the same period and up to the same date, we did not experience any breach of confidential client information or any other client information-related incidents which could cause a material adverse effect on our business, financial condition, or results of operations.

During the Track Record Period and up to the Latest Practicable Date, our PRC Legal Advisor is of the view that we have complied in all material respects with the applicable laws and regulations concerning data privacy, cybersecurity, and data security. Our PRC Legal Advisor have confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to data privacy and had been in compliance with the relevant PRC laws and regulations in all material aspects in this regard.