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INNOCARE

诺诚健华

InnoCare Pharma Limited

諾誠健華醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9969)

**ANNUAL RESULTS ANNOUNCEMENT
FOR THE YEAR ENDED 31 DECEMBER 2022**

The board (the “**Board**”) of directors (the “**Directors**”) of InnoCare Pharma Limited (the “**Company**”, and together with its subsidiaries, the “**Group**”) is pleased to announce the audited consolidated results of the Group for the year ended 31 December 2022 (the “**Reporting Period**”), together with the comparative figures for the year ended 31 December 2021. The consolidated financial statements of the Group for the Reporting Period have been reviewed by the Board and Audit Committee of the Company and confirmed by the Company’s auditors.

In this announcement, “we”, “us” and “our” refer to the Company and where the context otherwise requires, the Group. Certain amount and percentage figure included in this announcement have been subject to rounding adjustments or have been rounded to one or two decimal places, as appropriate. Any discrepancies in any table, chart or elsewhere totals and sums of amounts listed therein are due to rounding. Unless otherwise defined herein, capitalised terms used in this announcement shall have the same meanings as those defined in the Prospectus.

FINANCIAL HIGHLIGHTS

	2022 RMB’000	2021 RMB’000
Revenue	625,404	1,043,033
Other income and gains	198,199	217,938
Selling and distribution expenses	(438,611)	(298,463)
Research and development costs	(639,139)	(721,584)
Administrative expenses	(181,556)	(139,815)
Other expenses (mainly are unrealized exchange loss)	(291,167)	(1,271)
Loss for the year	(893,727)	(66,679)
Adjusted (loss)/profit for the year (as illustrated under “ Non-HKFRSs Measures ”)	(473,691)	2,630

Revenue

Our sales of Orelabrutinib increased by 163.6% to RMB565.9 million for the year ended 31 December 2022, compared to RMB214.7 million for the year ended 31 December 2021. Total revenue was RMB625.4 million for the year ended 31 December 2022, compared to RMB1,043.0 million for the prior year. The decrease of RMB417.6 million in total revenue was primarily attributable to the revenue generated from the business collaboration, decreased from RMB776.0 million for the year ended 31 December 2021 to nil for the year ended 31 December 2022.

Other Income and Gains

Our other income and gains decreased from RMB217.9 million for the year ended 31 December 2021 to RMB198.2 million for the year ended 31 December 2022, primarily attributable to (i) foreign exchange gain from RMB57.1 million in 2021 to nil in 2022; (ii) an increase of RMB8.4 million in investment income from the investments in wealth management products from RMB0.07 million in 2021 to RMB8.5 million in 2022; (iii) RMB29.9 million increase in recognized government grants from RMB16.3 million in 2021 to RMB46.2 million in 2022; and (iv) RMB1.8 million increase in the interest income from RMB135.1 million in 2021 to RMB136.9 million in 2022.

Total Expenses

Our total expense, including research and development costs, selling and distribution expenses, administrative expenses and other expenses, increased from RMB1,161.1 million for the year ended 31 December 2021 to RMB1,550.5 million for the year ended 31 December 2022, primarily due to the expansion of our clinical trials, the increase in market research and market promotion expense, the increase of personnel cost, and offset by decrease of license-in expense. Such change was mainly resulted from (i) the change in other expense from a gain of RMB57.1 million in 2021 to an unrealized loss of RMB290.6 million in 2022, due to USD appreciation against RMB when exchanging our overseas companies' RMB balance to its functional currency USD; (ii) RMB115.4 million increase of clinical trial and employee cost from RMB304.5 million to RMB419.9 million, offset by decrease of license-in and collaborative expense from RMB273.0 million to RMB2.5 million and (iii) RMB140.1 million increase of selling and distribution expenses, including employee expense and marketing promotion cost due to the generation of increased revenue, from RMB298.5 million to RMB438.6 million.

Loss for The Year

Based on the factors described above, our loss for the year increased from RMB66.7 million for the year ended 31 December 2021 to RMB893.7 million for the year ended 31 December 2022. Taking no account of the impact of share-based compensation and unrealized foreign exchange, the loss for the year (as illustrated under "Non-HKFRSs Measures") decreased from a profit of RMB2.6 million for the year ended 31 December 2021 to a loss of RMB473.7 million for the year ended 31 December 2022.

Non-HKFRSs Measures

To supplement the Group's consolidated financial statements, which are presented in accordance with HKFRSs, we also use the adjusted total loss for the year as an additional financial measure, which is not required by, or presented in accordance with HKFRSs. We believe that these adjusted measures provide useful information to shareholders and potential investors in understanding and evaluating our consolidated results of operations in turn as they help our management.

Adjusted total loss for the year represents the total loss for the year excluding the effect of certain non-cash items, namely the unrealized foreign exchange and share-based compensation expense. The term adjusted total loss for the year is not defined under HKFRSs. The use of this non-HKFRSs measure has limitations as an analytical tool, and you should not consider it in isolation from, or as a substitute for analysis of, our results of operations or financial condition as reported under HKFRSs. Our presentation of this adjusted figure may not be comparable to similarly titled measures presented by other companies. However, we believe that this non-HKFRSs measure reflects our normal operating results by eliminating potential impacts of items that our management do not consider to be indicative of our normal operating performance, and thus, facilitate comparisons of normal operating performance from period to period and company to company to the extent applicable. The table below sets forth a reconciliation of total loss to adjusted total loss for the years indicated:

	2022 RMB'000	2021 <i>RMB'000</i>
Loss for the year	(893,727)	(66,679)
Adjust:		
Unrealized exchange loss/(gain)	290,559	(57,135)
Share-based compensation expense	129,477	126,444
Adjusted loss for the year	(473,691)	2,630

BUSINESS HIGHLIGHTS

During the fiscal year, we continued advancing our robust pipeline which consist of 13 valuable assets, including 2 commercialized products, more than 30 ongoing global trials in various clinical stages, and business operations with consistently strong execution and a clear growth strategy in aspects of research and development (“R&D”), manufacturing, commercialization, and collaboration, including the following milestones and achievements:

DEVELOPING B-CELL AND T-CELL PATHWAYS IN AUTOIMMUNE DISEASES

We have fortified our powerful discovery engine in the global frontier targets for the development of autoimmune therapeutics through B-cell and T-cell pathways for the purpose of providing the first-in-class or best-in-class treatments to the massive unmet clinical needs with a promising market potential in global and/or regional markets.

Orelabrutinib

As of the date of this announcement, the 12-week interim analysis topline data of the multiple sclerosis (“MS”) global Phase II trial had met the primary endpoint. Our brain-penetrating BTK inhibitor Orelabrutinib significantly reduced disease activity in a Phase II trial in relapsing multiple sclerosis patients. The primary objective of detecting significant reduction in cumulative number of new gadolinium (“Gd”) + T1 lesions at week 12 compared to placebo was met in all three active treatment groups in a dose-dependent manner. The 80 mg QD group showed the highest reduction of 92.1% (p=0.0006), supporting further development.

The Phase IIa trial for systemic lupus erythematosus (“SLE”) delivered positive results in March 2022. The study showed that Orelabrutinib was safe and well tolerated. Its efficacy was demonstrated by remarkable SLE Responder Index (“SRI”)-4 response rates in a dose dependent manner. The detailed information was presented as a late-breaking oral presentation at the European Alliance of Associations for Rheumatology (“EULAR”) in June 2022. At the end of 2022, with the completion of the discussion with the Center for Drug Evaluation (“CDE”) regarding next stage development protocol for Orelabrutinib for SLE, we initiated the Phase IIb trial for a larger population in mainland China.

We are pursuing Phase II clinical trial of Orelabrutinib for the treatment of primary immune thrombocytopenia purpura (“ITP”) and have achieved proof of concept (“PoC”). The primary endpoint will be concentrated on the proportion of subjects with platelet count $50 \times 10^9/L$ (platelet count should be detected at least twice consecutively, with an interval of at least 7 days). As of cut-off date on 6 February 2023, the overall 36.4% (12 out of 33 patients) met the primary endpoint, while 40% (6 out of 15) patients at the 50 mg arm.

ICP-332

ICP-332 is a novel tyrosine kinase 2 (“**TYK2**”) inhibitor that is developed for the treatment of various T cell related autoimmune disorders. We completed the Phase I clinical trial in March 2022. Based on the data of safety, PK/PD, and biomarkers with no significant decrease of platelet and hemoglobin (JAK-2 related AE) in the Phase I study, we initiated Phase II study in atopic dermatitis (“**AD**”) in China in the second half of 2022.

ICP-488

ICP-488 is a potent and selective TYK2 allosteric inhibitor binding to the pseudo kinase JH2 domain of TYK2 and blocks IL-23, IL12, type 1 IFN and other cytokine receptors. We plan to develop ICP-488 for the treatments of various autoimmune diseases.

The first subject was dosed in August 2022 and the study enrollment of the Phase I trial is ongoing in China as of the date of this announcement. The single ascending doses (“**SAD**”) part, two cohorts of multiple ascending doses (“**MAD**”) have been completed. Patients with psoriasis will be treated at selected doses.

BUILDING A LEADING FRANCHISE IN HEMATO-ONCOLOGY

With Orelabrutinib as a backbone therapy and the support of our abundant pipeline in hemato-oncology, such as ICP-248, ICP-490, ICP-B02, Tafasitamab and potential future internal and external pipeline development, we aim to become a leading player in hemato-oncology in China and worldwide by covering non-Hodgkin lymphoma (“**NHL**”), multiple myeloma (“**MM**”), and leukemia segments by single or combo therapy. A particular combination therapy toolkit is well designed and aims to position a full coverage of diffuse large B-cell lymphoma (**DLBCL**).

NHL – indolent lymphoma

Orelabrutinib

- Leveraging the strong sale momentum after entered in NRDL in 2022, Our core product 宜諾凱® (Orelabrutinib, BTK inhibitor) generated a product revenue of RMB565.9 million for the year ended 31 December 2022, an increase of 164% compared to RMB214.7 million in the same period of 2021. The strong sales growth was mainly driven by the smooth implementation of the updated National Reimbursement Drug List (“**NRDL**”), active and effective market penetration carried out by our in-house commercialization team, and broad use recommendation by the 2021 Chinese Society of Clinical Oncology (“**CSCO**”) Diagnosis and Treatment Guidelines for Malignant Lymphoma (the “**Guidelines**”).
- The new drug application (“**NDA**”) for relapsed and/or refractory marginal zone lymphoma (“**r/r MZL**”) was accepted by the National Medical Products Administration (“**NMPA**”) in August 2022 and is currently under the priority review.
- We are conducting a Phase III registrational trial for first-line treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (“**CLL/SLL**”), which is more than halfway through patient enrollment in China, comparing Orelabrutinib monotherapy versus rituximab plus chlorambucil.

- In the U.S., the patient enrollment of Phase II registrational trial for relapsed and refractory mantle cell lymphoma (“**r/r MCL**”) is ongoing and we expect to submit the NDA in next year.
- A clinical trial of the combination of Orelabrutinib with anti-programmed death protein-1 (“**anti-PD-1**”) monoclonal antibody in refractory or relapsed primary central nervous system lymphoma is ongoing, and the preliminary results of the study was presented at European Hematology Association (“**EHA**”).

NHL – aggressive lymphoma/DLBCL

Orelabrutinib

- We are in a progress of a Phase III registrational trial in China for the first-line treatment of MCD subtype diffuse large B-cell lymphoma (“**DLBCL**”) comparing Orelabrutinib in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (“**R-CHOP**”) versus R-CHOP. The real-world data regarding Orelabrutinib in combination with R-CHOP for MCD DLBCL were posted at American Society of Clinical Oncology (“**ASCO**”) in June 2022. For the initial 14 patients, the complete response rate (“**CRR**”) for the first-line and second-line patients were 75% and 66.67%, respectively.

ICP-B04 (Tafasitamab (“CD19”) (Minjuvi®))

- Tafasitamab, in combination with Lenalidomide, was the first approved second-line treatment for DLBCL in the U.S. and obtained the approval in Europe for the treatment of adults with r/r DLBCL who are not eligible for autologous stem cell transplantation (“**ASCT**”). In China, Tafasitamab in combination with Lenalidomide was officially included as a class II recommended regimen for the treatment of adult patients with r/r DLBCL who are ineligible for ASCT in the 2022 CSCO Guidelines.
- Tafasitamab, in combination with lenalidomide is not approved by the National Medical Products Administration (NMPA) for any indication in China, except that the combination has been approved by the Department of Health, the Hong Kong Special Administrative Region, China for adult patients with relapsed or refractory diffuse large B-cell lymphoma (“**DLBCL**”) who are not eligible for ASCT. The Hong Kong approval of Tafasitamab and lenalidomide will not only provide access to eligible DLBCL patients in the region but may also assist patient access in the Greater Bay Area soon. Additionally, under the early access program in Boao Lecheng International Medical Tourism Pilot Zone, prescriptions of Tafasitamab in combination with lenalidomide were filled in China at the Ruijin Hainan Hospital for an eligible DLBCL patients. Moving forward, we will accelerate the registrational trial in China in the hopes of meeting more unmet medical needs, if approved.

ICP-B02 (CM355)

- ICP-B02 is a CD20xCD3 bispecific antibody. The Phase I dose escalation is progressing with the fourth cohort which has been completed in January 2023. So far, the almost complete B-cell depletion was observed in patients treated with low dose of ICP-B02. The IND application for ICP-B02 subcutaneous (“SC”) formulation was approved by the CDE in March 2023.

Multiple Myeloma (“MM”)

ICP-490

- ICP-490 is a proprietary, orally available small molecule that modulates the immune system and other biological targets through multiple mechanisms of action. The investigational new drug (“IND”) application for oncology indications was approved by the CDE in July 2022 and the Phase I dose escalation study was initiated in February 2023.

Leukemia

ICP-248

- ICP-248 is a novel, orally bioavailable B-cell lymphoma-2 (“BCL-2”) selective inhibitor. BCL-2 is an important part of apoptotic pathway and is overexpressed in a variety of hematologic malignancies. The IND application for ICP-248 was accepted by the CDE in July 2022 and Phase I patient enrollment mainly targeting chronic lymphocytic leukemia and mantle cell lymphoma is ongoing.

BUILDING A COMPETITIVE DRUG PORTFOLIO FOR SOLID TUMOR TREATMENT IN CHINA AND WORLDWIDE

We strived to expanding the breadth of our pipeline covering solid tumor diseases areas through the precision medicine to provide the right medicine to the right patient at the right time. We believe the potential best-in-class molecules ICP-192 and ICP-723 will enable us to establish a solid footprint in the field of solid tumor treatment.

ICP-192 (Gunagratinib)

In the middle of January 2023, we presented the ICP-192 data from an ongoing Phase IIa dose-expansion study of Gunagratinib in patients with cholangiocarcinoma (“CCA”) at ASCO-GI 2023. Gunagratinib is safe and well-tolerated with high response rate (52.9%) compared to other approved FGFR inhibitors in previously treated patients with locally advanced or metastatic CCA harboring FGFR2 gene fusions or rearrangements. Currently, we are conducting ICP-192 registrational trial in CCA in China and undergoing several Phase I/II clinical studies in China, the U.S., and Australia.

ICP-723 (Zurletrectinib)

In the Phase I dose escalation study, dosage has been escalated up to 20 mg with no DLT observed. Phase II dose expansion study is ongoing with RP2D being determined as 8 mg. As of 30 December 2022, 75% ORR (9 PR in 12 patients) was observed in adult patients with various cancers carrying NTRK fusion and 77.8% ORR (7 PR in 9 patients) was observed at RP2D. The IND submission for additional pediatric population (<12 years old) was accepted by CDE in January 2023 and we intend to communicate with CDE on further registrational trial.

To benefit more patients, our rapidly maturing early-stage pipeline including the cornerstone therapy ICP-189 and ICP-B05, and ICP-033 immune-oncology treatment should enable us to provide a competitive treatment solution for a large array of solid tumors for both China and global patients.

ICP-189

ICP-189 is a potent oral allosteric inhibitor of SHP2 with potential synergistic combinations with a range of targeted therapies or immunotherapies. We are conducting a Phase Ia dose escalation study to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of ICP-189 in patients with advanced solid tumors in China. As of 8 February 2023, dosage has been escalated up to 40 mg with no DLT observed and demonstrated favorable PK profile and long half-life. Preliminary efficacy was observed in ICP-189 monotherapy. 1 patient with cervical cancer in 20 mg dose cohort achieved confirmed PR.

ICP-B05 (CM369)

ICP-B05 is an anti-CC chemokine receptor 8 (“**CCR8**”) monoclonal antibody, a potential first-in-class drug co-developed with KeyMed as a monotherapy or in combination with other therapies for the treatment of various cancers. The IND was approved in the third quarter of 2022. We are conducting the Phase I clinical trial to evaluate the safety, tolerability, pharmacokinetic characteristics, and efficacy of ICP-B05 in subjects with advanced liquid and solid tumors.

MANAGEMENT DISCUSSION AND ANALYSIS OVERVIEW

OVERVIEW

InnoCare is a commercial stage biopharmaceutical company committed to discovering, developing and commercializing potential best-in-class and/or first-in-class drugs for the treatment of cancers and autoimmune diseases, being two major therapeutic areas with significant market opportunity and synergies. Led by a well-known management team of seasoned industry executives, we have built a fully integrated biopharmaceutical platform with strong in-house R&D, clinical development, manufacturing and commercialization capabilities. Our vision is to become a global biopharmaceutical leader that develops and delivers innovative therapies for patients worldwide.

Leveraging our management team's global vision and local expertise, we have built a differentiated and balanced drug portfolio and have launched our first product Orelabrutinib in China. In addition, we have launched the second commercialized product Tafasitamab in a designated province in China for prior clinical use. Our drug candidates target both novel and evidence-based biological pathways. Our discovery and development efforts are focused on drug candidates with evidence-based targets that have the potential to be best-in-class from a safety and efficacy perspective. We also devote significant efforts to identifying novel targets and developing therapies with global breakthrough potential.

- **We have continued to expand our commercial portfolio by launching the second product and maintain strong revenue growth performance of the flagship product in the first-year inclusion of NRDL.** During the fiscal year of 2022, our core product Orelabrutinib accelerated fast growth in both revenue and volume with an annual revenue growth of 163.6% compared with 2021. The global first approved CD19 antibody Tafasitamab for the treatment of second line of DLBCL was successfully launched in the priority use territory of Hainan province in mainland China and further granted BLA approval in Hong Kong. The rapid movement towards market validated our confidence and capability in commercialization.
- **We have enriched the robust pipeline with 13 clinical stage assets, keep pushing towards the late-stage innovative trials ahead, and achieved positive proof of concept (“PoC”) data including MS and ITP for several promising assets across three focused therapeutics areas.** We have advanced the assets in pivotal or registrational trial including Orelabrutinib in 1L DLBCL-MCD, 1L CLL/SLL, 1L MCL, r/r MZL, r/r WM, and r/r MCL in U.S. and ICP-192 in cholangiocarcinoma registrational trial. Additionally, we achieved positive PoC data readouts for Orelabrutinib in SLE that enable us to keep moving forward to pursue the first-in-class treatment. The 12-week interim analysis topline data of the MS global PoC trial had met the primary endpoint and we anticipate to disclose the full detailed data packages in the second quarter of 2023. For ITP, our Orelabrutinib achieved the favorable Phase II PoC data readout, which may lead to a potential best-in-class BTKi.
- **We have rolled out development for the global and high potential early-stage assets and accelerated the development of TYK2 assets ICP-332 and ICP-488 with positive preliminary data readouts.** Besides, other novel targets and platforms including but not limited to CD3xCD20, BCL-2, E3 Ligase, CCR8, and SHP2 are moving towards the next stage.

- **We have further enhanced our fully integrated platform from different aspects.** In 2022, while keeping our cost-effective core, we doubled the research scientists in drug discovery team and expanded the clinical team to further strengthen our R&D capacity globally. By leveraging the two exclusive strategic collaborations with leading academic laboratories for target identification, several projects targeting global first-in-class targets are under different development stages. We have two manufacturing sites in Beijing and Guangzhou to support CMCs of our pipeline and inline projects efficiently. To fully maximize the value of our first-in-class and/or best-in-class assets, we have expanded to approximately 300 in-house commercialization members to present.
- **We have maintained in a healthy financial position with a long-term cash runway.** After the RMB Shares of the Company have been successfully listed on Shanghai Sci-Tech Innovation Board (“**STAR**”) in September 2022, we have more than RMB9.0 billion cash and cash equivalents on hand. The healthy financial position and consistently efficient capital allocation provide us flexibility on the long-term strategy.

2023 OUTLOOK AND FUTURE DEVELOPMENT

Approaching the eighth year of the establishment of the Company, we anticipate that in 2023, the group will continue to be a promising year for the commercialized and pivotal stage pipeline and mark a transformative year for the Company to become InnoCare version 2.0 from 1.0 by further expanding our global R&D footprint, commercialization, and manufacturing capabilities. To accomplish our vision of becoming a global biopharmaceutical leader that develops and delivers innovative therapies for patients worldwide, we will focus on pursuing the following aspects:

Developing B-cell and T-cell Pathways in Autoimmune Diseases

According to the Multiple Sclerosis International Federation (“**MSIF**”), more than 2.8 million people around the world are affected by MS currently. According to Frost & Sullivan Analysis, global market of MS drugs reached US\$23.0 billion in 2018, and it is expected to increase to US\$31.7 billion by 2030. BTK plays an important role in the development and function of B cells, macrophages, and microglia, which are involved in the immunopathological characteristics of MS. We believe BTK inhibitors have the potential to transform the treatment paradigm of MS. Orelabrutinib, which has demonstrated sustained anti-inflammatory activity, excellent safety profile and a superior Brain Blood Barrier (“**BBB**”) penetration capability, has the potential to become the best-in-class BTK inhibitor for MS. We are quickly progressing our Phase II MS global clinical trial and hopefully Orelabrutinib will be established as the best-in-class BTK inhibitor for MS treatment in the future.

Orelabrutinib’s favorable safety profile and established B-cell pathway regulation capability enabled us to aggressively pursue its application in treating various auto-immune disease. Based on the positive results from the Phase IIa SLE clinical trial, we believe Orelabrutinib could potentially become the first-in-class BTK inhibitor in the treatment of SLE and we are actively moving forward with further development scheme. Further, we have initiated Phase II trials in other autoimmune indications including ITP and NMOSD.

In addition to Orelabrutinib, we are exploring the possibility of treating autoimmune diseases induced by T-cell dysfunctions with other potential candidates. We are developing ICP-332 and ICP-488, for the treatment of various T-cell mediated autoimmune diseases, such as AD, psoriasis, SLE, LN, and IBD, etc. With both Orelabrutinib as a B-cell pathway regulator and ICP-332 and ICP-488 as T-cell pathway regulators in hand, we believe we are well-positioned to provide oral drug solutions for the substantial unmet medical needs in autoimmune diseases.

Building A Leading Franchise in Hemato-oncology

With Orelabrutinib as a backbone therapy and the support of our abundant pipeline in hemato-oncology, such as ICP-248, ICP-490, ICP-B02, Tafasitamab and potential future internal and external pipeline development, we aim to become a leading player in hemato-oncology in China and worldwide by covering MM, NHL, and leukemia markets. Leveraging the strong sales momentum after entering the NRDL in 2022, we will continue to accelerate the sales of Orelabrutinib (宜諾凱®) in China. We have a broad clinical program for Orelabrutinib in various B-cell malignancies in China to broaden its indication including MZL, WM, first-line treatment of CLL/SLL, MCL and MCD subtype DLBCL, and etc. We are actively propelling the timely approval of Orelabrutinib in the U.S. for r/r MCL and actively pursuing potential combination therapy partners to maximize the value of its superior clinical profile in NHL market ex-China.

Building A Competitive Drug Portfolio for Solid Tumor Treatment in China and Worldwide

We believe the potential best-in-class molecules ICP-192 and ICP-723 will enable us to establish a solid footprint in the field of solid tumor treatment with the precision medicine. Our rapidly maturing early-stage pipeline including the cornerstone therapy ICP-189 and ICP-B05, and ICP-033 immune-oncology treatment should enable us to provide a competitive treatment solution for a large array of solid tumors for both China and global patients.

Continuing To Expand Our Pipeline Through In-House Discovery and Business Development Efforts

We will continue to develop our multiple candidates that are currently at IND-enabling stage and generate new molecular entities from our proven in-house drug discovery platform.

To further enhance our pipeline and optimize our operational efficiency, we will actively pursue in-licensing opportunities that will complement our existing portfolio. A strong emphasis will be placed on licensing assets that could allow us to fully leverage our established clinical development, commercialization, and manufacturing capabilities, and those have potential synergies with our current pipeline for combination therapies.

Establishing In-House Biological Drug R&D Capability Through Internal and External Efforts

With the long-term goal of becoming a world leading biopharma company, we believe it is necessary to build our internal biological drug R&D capability. Collaborative activities surrounding ICP-B02, ICP-B05 and Tafasitamab have clearly demonstrated our commitment and provided us a great starting point. Building an internal talent team and necessary infrastructure for biological drugs is well underway.

BUSINESS OVERVIEW

ORELABRUTINIB COMMERCIALIZATION ACHIEVEMENTS AND MILESTONES

Orelabrutinib (宜諾凱®), our first commercialized product, a highly selective, irreversible BTK inhibitor was successfully included in China's NRDL in 2021 for the treatment of patients with r/r CLL/SLL and r/r MCL. Total revenue was recorded as RMB625.4 million for the year ended 31 December 2022 which Orelabrutinib generated a sales of RMB565.9 million for the fiscal year end of 2022, representing a 163.6% growth comparing to 2021. With an in-house team of approximately 250 experienced sales and marketing members, Orelabrutinib's promotion coverage had rapidly penetrated more than 300 cities and more than 1,500 nationally leading hospitals, and over 6,000 doctors were well educated. We expect that the NRDL inclusion and our strengthened commercialization capability could enable us to maintain the strong growth momentum of Orelabrutinib sales in 2023 and beyond through broadened patient access, accelerated market penetration, and enhanced duration of treatment (“DOT”).



(宜諾凱®, Orelabrutinib, BTK inhibitor)

Orelabrutinib (宜諾凱®) was included in the CSCO Guidelines and has been recommended as a Class I treatment for r/r CLL/SLL and r/r MCL, and as one of the recommended BTK inhibitor to combine with chemotherapy for the treatment of r/r DLBCL and pCNSL.

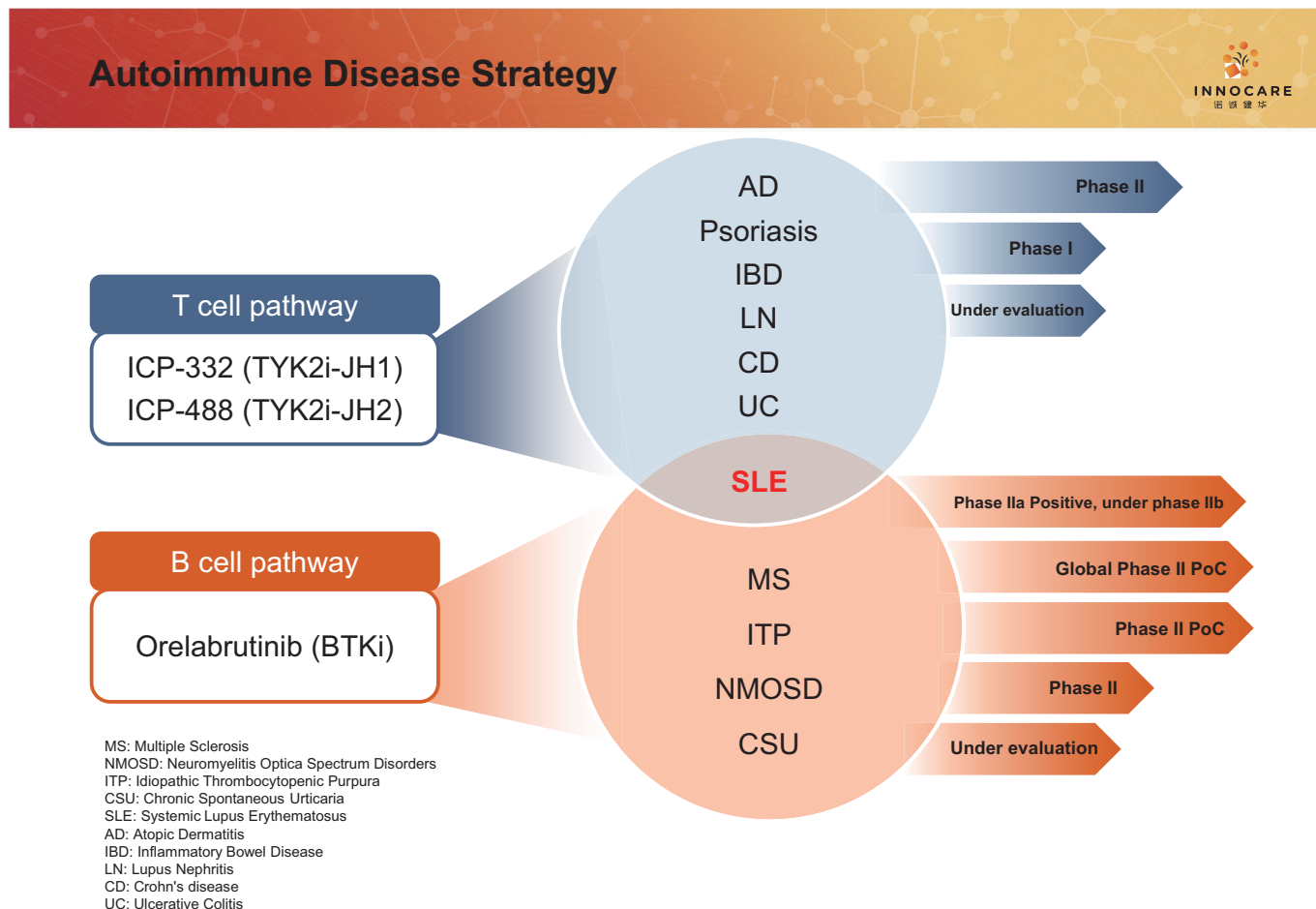
PRODUCT PIPELINE

Our current pipeline drugs cover a variety of novel and validated therapeutic targets and drug modalities including monoclonal antibodies, bispecific antibodies, and small molecules for the treatment of various autoimmune diseases, hemato-oncology and solid tumors.



Developing B-cell and T-cell Pathways in Autoimmune Diseases

We have fortified our powerful discovery engine in the global frontier targets for the development of autoimmune therapeutics through B-cell and T-cell pathways for the purpose of providing the first-in-class or best-in-class treatments to the massive unmet clinical needs with a promising market potential in global and/or regional markets.



For the autoimmune diseases, by leveraging Orelabrutinib's favorable safety profile, high selectivity, central nervous system ("CNS") penetrance, we have established B-cell pathway regulation capability, enabling us to actively pursue its application in treating various autoimmune diseases. Based on the positive results from the Phase IIa SLE clinical trial, we believe Orelabrutinib could potentially become the first-in-class BTK inhibitor for the treatment of SLE and a Phase IIb trial has been initiated in China. We are advancing the global Phase II PoC development of Orelabrutinib in MS. Further, we are progressing Phase II trials in other autoimmune indications including ITP, NMOSD, and potentially further explore chronic spontaneous urticaria ("CSU").

Meanwhile, we are exploring the possibility of treating autoimmune diseases induced by T-cell dysfunctions with other potential candidates. We are developing ICP-332 and ICP-488, two TYK2 inhibitors for the treatment of various T-cell mediated autoimmune diseases, such as AD, psoriasis, SLE, IBD, lupus nephritis ("LN"), Crohn's disease ("CD"), and ulcerative colitis ("UC").

With Orelabrutinib as a B-cell pathway regulator and ICP-332 and ICP-488 as T-cell pathway regulators in hand, we believe we are well positioned to provide oral drug solutions for the substantially unmet medical needs in autoimmune diseases.

B Cell Pathway – Orelabrutinib for Autoimmune Diseases

BTK is a member of the TEC family and is expressed in B lymphocytes, mast cells, macrophages, monocytes, and neutrophils. It is a key kinase in the BCR signaling pathway, and regulates B cell proliferation, survival, differentiation, and cytokine expression. The abnormal activation of BTK related signaling pathways can mediate autoimmune diseases. BTK has become a new and popular therapeutic target for autoimmune diseases.

Because of Orelabrutinib's high target selectivity and good safety profile, we are evaluating it as a novel therapy for the treatment of various autoimmune diseases.

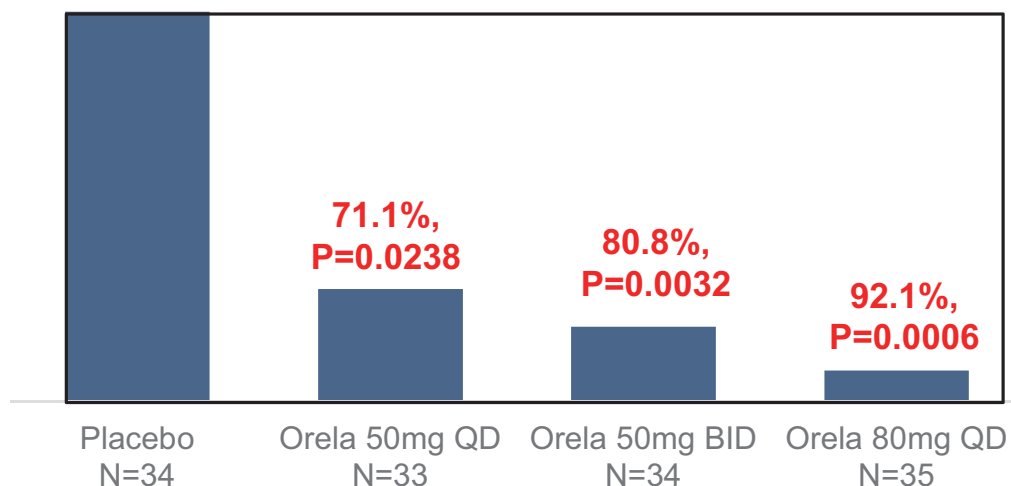
Orelabrutinib for MS

Current Status

We are evaluating Orelabrutinib in MS with a global phase II study. It is a randomized, double-blind, placebo-controlled Phase II clinical study to evaluate the use of Orelabrutinib in patients with relapsing multiple sclerosis (“**RMS**”) regarding its efficacy, safety, tolerability, pharmacokinetics and biological activity. The study contains two parts, including a core part and an open-label extension (“**OLE**”) part. The Patients with RMS in the core part of the study will be randomly assigned to 1 of 4 groups(placebo, Orelabrutinib 50 mg QD, Orelabrutinib 50 mg BID and Orelabrutinib 80 mg QD) at 1:1:1:1 ratio. The OLE part is an open-label, single treatment arm study to enroll patients who have completed the Week 24 visit in the core part for continued treatment and collect additional long-term safety and efficacy data. The primary outcome measure is the cumulative number of new GdE T1 MRI brain lesions, which intends to evaluate the efficacy of Orelabrutinib on the cumulative number of new gadolinium-enhancing (“**GdE**”) T1 magnetic resonance (“**MRI**”) brain lesions versus placebo over 12 weeks of treatment.

In the planned interim analysis, a total of 136 patients' data were analyzed. The relative reduction for the cumulative number of new Gd+ T1 lesions within Week 12 as compared with placebo were 71.1% in the Orelabrutinib 50 mg QD group (p=0.0238), 80.8% in the Orelabrutinib 50 mg BID group (p=0.0032), and 92.1% in the Orelabrutinib 80 mg QD group (p=0.0006), which indicated the trend of dose-dependent improvement.

Primary Endpoint – Cumulative Number of New Gd+ T1 Brain Lesions at Week 12
Relative reduction% compare to placebo
(95% CI¹)



Note: 1CI: Confidence Interval

QD = Once Daily, BID = Twice daily. Percent reduction and p-value estimated from a Poisson regression model with Pearson scale parameter and offset for log number of scans adjusted for baseline number of lesions.

The 24-week results will be available in May, 2023.

Different Molecule’ Phase II Study Results in Relapsing Multiple Sclerosis (“RMS”)

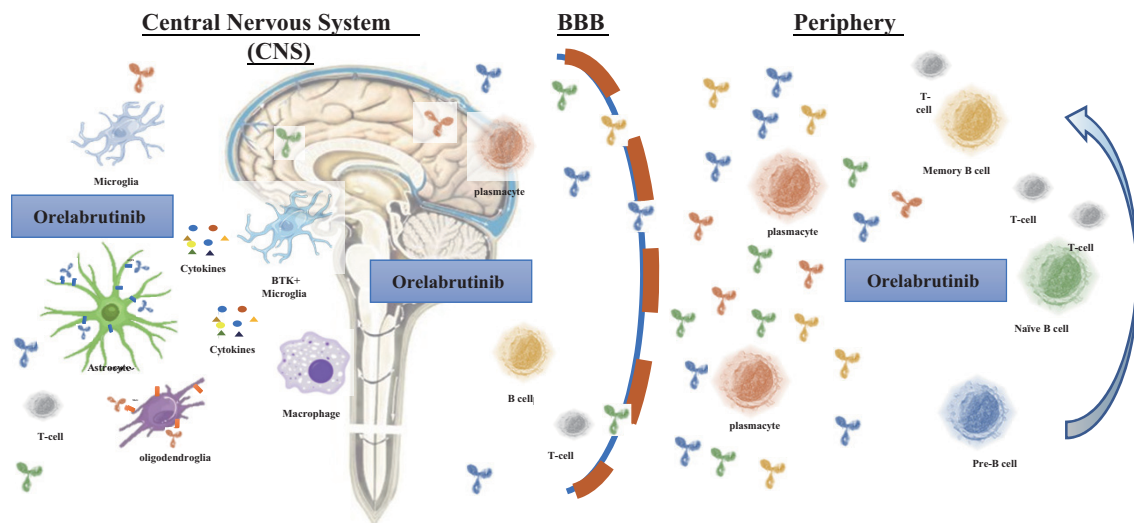
Therapy	Design, Duration ¹	Primary endpoint	Relative Reduction in T1 lesions vs. PBO	Dose	Company
Orelabrutinib BTKi	Placebo-controlled(N = 136), 24Wk + ext	Cumulative Gd+lesions at Wk12	92.1%	80mg QD	InnoCare
Tolebrutinib BTKi	Placebo-controlled for 4Wk, with 12Wk cross-over (N=130), 16Wk + ext	Dose-response for Gd+ lesions at Wk 12	85% ⁽²⁾	60mg QD	Sanofi
Evobrutinib BTKi	Placebo-controlled + open label DMF (N = 267),24Wk + ext	Cumulative Gd+ lesions at Wk12, 16, 20, and 24	70% ⁽³⁾	75mg qd (56% at 75mg bid)	Merck KGaA
Ocrelizumab Anti-CD20	Placebo-controlled + Inf-b1a reference arm (N=218), 24Wk + ext	Cumulative Gd+ lesions at Wk 12, 16, 20, and 24	89% ⁽⁴⁾	600mg q6mo	Roche
Ofatumumab Anti-CD20	Placebo-controlled (N=231), 24Wk + ext	Cumulative Gd+ lesions at Wk 12	65% ⁽⁵⁾⁽⁶⁾ 91% ⁽⁷⁾	60mg q12w	Novartis
Siponimod S1PR	Placebo-controlled, adaptive, doseranging (N = 297), 6m + ext	Dose-response for CUAL at 3 mo	72% ⁽⁸⁾	2mg qd	Novartis
Dimethyl Fumarate	Placebo-controlled(N = 257),24Wk + ext	Cumulative Gd+ lesions at Wk12, 16, 20, and 24	69% ⁽⁹⁾	240mg tid	Biogen
Fingolimod S1PR	Placebo-controlled (N = 281), 6m + ext	Cumulative Gd+ lesions monthly for 6 months	61% ⁽¹⁰⁾ 88% at mo. 6	5mg qd	Novartis
Teriflunomide	Placebo-controlled (N = 179), 36Wk + ext	# of CUAL per MRI scan	61% ⁽¹¹⁾	14mg qd	Sanofi

Notes: (1) www.clinicaltrials.gov; (2)Sanofi’s R&D held on April 23, 2020;(3) MontalbanX, et al. N Engl J Med 2019; 380:2406-2417;(4) KapposL, et al. Lancet 2011;378:1779-87 (5) Bar-Or A. et al, Neurology 2018;90:e1805-e1814; (6)Endpoint with full data (0-12 Wks) (7) Post hoc data (4-12 wks);(8) Selmaj K, et al Lancet Neurol 2013;12:756-767;(9) Kappos L, et al. Lancet 2008;372(9648):1463-72;(10) Kappos L, et al. N Engl J Med 2006; 355:1124-40;(11) O’Connor P, et al. Neurology 2006;66(6)

Mechanism

MS is a disease in which the body's immune system eats away at the protective sheath that covers the nerves. In MS, the resulting nerve damage disrupts communication between the brain and the body. Multiple sclerosis causes many different symptoms, including but not limited to movement disorder, brain injury, feeling abnormal, visual impairment, language disability, abnormal bowel function, and urinary system abnormalities, etc. The symptoms, severity, and duration can vary from person to person. Some people may be symptom free most of their lives, while others can have severe chronic systems that never go away. Physical therapy and medications that suppress the immune system can help with symptoms and slow disease progression.

Orelabrutinib has the potential to act in both CNS and periphery for demyelinating diseases. Its high target selectivity, good PK profile and BBB penetration capability presents a promising option for treating MS. Based on the PK data of orelabrutinib in lymphoma patients, Orelabrutinib demonstrated superior plasma exposure and brain penetration than other inhibitors of BTK, including evobrutinib and tolebrutinib, at therapeutic dose, indicating Orelabrutinib could achieve deeper and more durable target occupancy in both periphery and CNS than evobrutinib and tolebrutinib.



BTKi	Company	Dose (mg)	Plasma concentration at 2 h (ng/mL)	CSF Conc. ~2h (ng/mL)
Orelabrutinib	InnoCare	150 QD	990	31.3
Evobrutinib	Merck KGaA	75 BID	115	3.21 ²
Tolebrutinib	Sanofi	120 QD	13.4	1.87 ¹

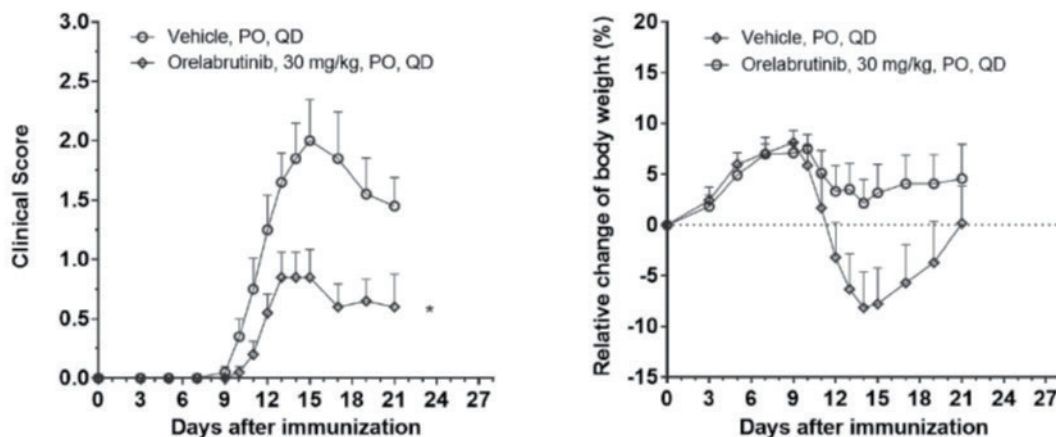
Notes:

1 doi: 10.1016/j.msard.2021.103000

2 Multiple Sclerosis and Related Disorders 51 (2021) 103001 Topic: Advances in therapy in MS; doi: 10.1016/j.msard.2021.103001

Experimental autoimmune encephalomyelitis (“EAE”) is the most common animal model of human MS as it is especially useful to investigate neuroinflammatory pathways. In the myelin oligodendrocyte glycoprotein (“MOG”) peptide-induced EAE mouse model, Orelabrutinib reduced EAE severity, as evidenced by decreases in clinical disease score and body weight loss.

Orelabrutinib’s Pre-clinical Efficacy in EAE Diseases Progression MS Mouse Model



So far, none of the available DMTs for the treatment of MS is free of potential hepatic toxic effects. Per the consolidation of FDA website information and *Biolato M, Bianco A, Lucchini M, Gasbarrini A, Mirabella M, Grieco A. The Disease-Modifying Therapies of Relapsing-Remitting Multiple Sclerosis and Liver Injury: A Narrative Review. CNS Drugs. 2021 Aug;35(8):861-880*, a total of 26 drugs were approved for the treatment of MS excluding the terminated drug usage. 24 out of 26 drugs’ labels contain drug-induced liver function problems. For instance, daclizumab and teriflunomide both contain a black box warning “**liver toxicity**”, while the other 22 drugs include warnings or precaution notes i.e., liver injury, liver function impairment, hepatotoxicity, autoimmune hepatitis, HBV reactivation and drug-induced liver injury, etc., with the remaining drug labels contain the adverse effect of liver enzymes elevation.

It is routine to screen and monitor liver function for DMTs. Per *Biolato M, Bianco A, Lucchini M, Gasbarrini A, Mirabella M, Grieco A. The Disease-Modifying Therapies of Relapsing-Remitting Multiple Sclerosis and Liver Injury: A Narrative Review. CNS Drugs. 2021 Aug;35(8):861-880*, the chart below demonstrates the ALT monitor requirement and frequency in relation to a few of the injective treatments, oral treatments, and even infusion treatments.

Agent	Liver function tests screening	ALT monitoring	Data in cirrhotic patients
Injective treatments			
Beta interferon	Yes	After I. 3. 6 months and periodically thereafter	Not available
Glatiramer acetate	No (but suggested)	No	Not available
Oral treatments			
Fingolimod	Yes	After I. 3. 6. 9. 12 months and bimonthly thereafter	Contraindicated in Child C patients
Teriflunomide	Yes	Every 2 weeks for 6 months, then bimonthly	Contraindicated in Child C patients Caution in fany liver disease
Dimethyl fumarate	Yes	Yes (suggested every 6 months)	Not available
Cladribine	Yes	No	Contraindicated in Child B and C patients
Infusional treatments			
Natalizumab	Yes	Monthly for first 3 months, quarterly thereafter	Not available
Alemtuzumab	Yes	Monthly up to 48 months from last infusion	Not available
Ocrelizumab	Yes	No (but suggested semiannually)	Use only in Child A patients

ALT alanine aminotransferase

Following written notification from the FDA in December 2022 requesting additional data, we are in the progress of providing the relevant information with the aim of lifting the partial clinical hold. On 17 February 2023, the amendments of protocol, IB and ICF for the global Phase II MS clinical trial was submitted to FDA and accepted. We are communicating closely with iDMC and iHAC to furnish the expert opinion and risk and benefit assessment. We will strive to provide more data to FDA in the purpose of resolving the partial clinical on hold for the cases paused in the U.S. sites and further resume other sites.

For a detailed overview of the said FDA relevant information, please see our announcement dated 23 December 2022 published on the website of the Stock Exchange and the Company.

Business Collaboration

On 13 July 2021, we entered into a license and collaboration agreement for Orelabrutinib for the potential treatment of MS with Biogen. Under the terms of the said agreement, Biogen will have exclusive rights to Orelabrutinib in the field of MS worldwide and certain autoimmune diseases outside of China (including Hong Kong, Macau and Taiwan), while we will retain exclusive worldwide rights to Orelabrutinib in the field of oncology and certain autoimmune diseases in China (including Hong Kong, Macau and Taiwan). We received a non-refundable US\$125 million upfront payment and is eligible to receive up to US\$812.5 million in potential development milestones and potential commercial payments should the collaboration achieve certain development, commercial milestones, and sales thresholds. We were also eligible to receive tiered royalties in the low to high teens' percentage on potential future net sales of any product resulting from the collaboration.

For a detailed overview of the said business collaboration with Biogen and detailed mechanism of Orelabrutinib, please see our announcement dated 13 July 2021 published on the website of the Stock Exchange and the Company.

On 15 February 2023, Biogen has notified us of its decision to terminate for convenience the Collaboration and License Agreement between the parties for the global development and commercialization of Orelabrutinib for the potential treatment of MS and other autoimmune diseases. Following the termination, we will regain all global rights granted to Biogen under the Agreement, including related intellectual property, decision-making regarding research and development, manufacturing, and commercialization, and commercial proceeds generated from Orelabrutinib. The parties will collaborate to complete the transition within 90 days. We welcome Orelabrutinib back to our autoimmune portfolio.

For a detailed overview of the said business collaboration with Biogen of Orelabrutinib, please see our announcement dated 15 February 2023 published on the website of the Stock Exchange and the Company.

In conclusion, with the ability to cross the blood brain barrier, Orelabrutinib has the potential to inhibit B cell and myeloid cell effector functions in the CNS, and may provide a clinically meaningful benefit in all forms of MS. The Phase II MS global OLE part study is ongoing. Given the encouraging clinical outcomes from multiple autoimmune trials, we remain confident and committed to accelerating the global development of Orelabrutinib as a potential best-in-class BTK inhibitor for MS and other autoimmune diseases.

Orelabrutinib for SLE

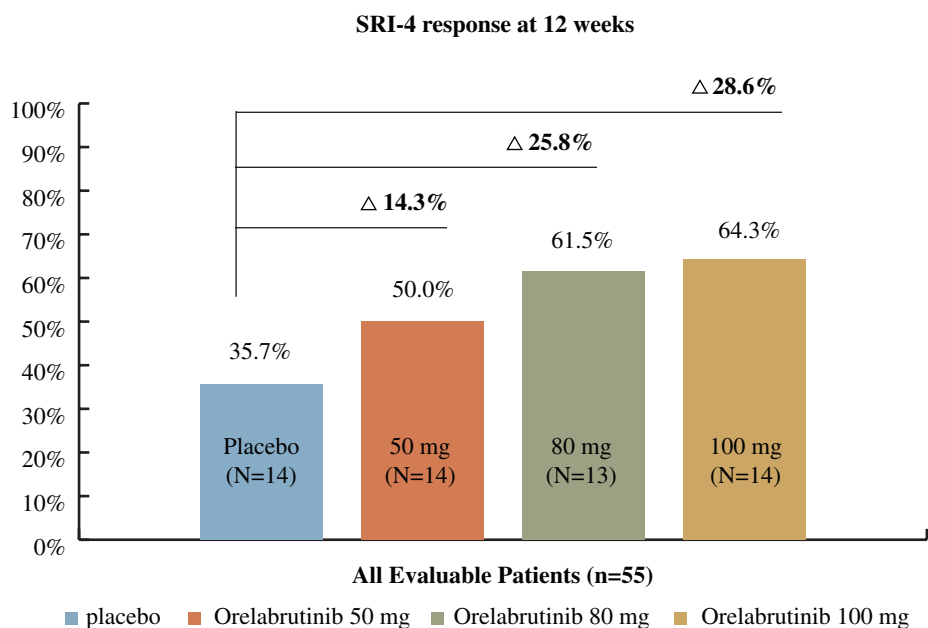
Orelabrutinib inhibits the BCR signaling cascade by binding to BTK, hence preventing the proliferation and activation of B cells in autoimmune diseases. Pre-clinical data demonstrated that Orelabrutinib has dose dependent effects on the improvement of kidney function, the inhibition of arthritis, and the reduction of inflammation in SLE mouse models.

Current Status

In China, Orelabrutinib Phase II trial for SLE was completed at the end of 2021 which showed positive results. The detailed information was presented through a late-breaking oral presentation at 2022 European Alliance of Associations for Rheumatology (“EULAR”). This is a randomized, double-blind, placebo-controlled, dose-finding study aimed to evaluate the safety and tolerability of Orelabrutinib in patients with mild to moderate SLE. The patients receiving standard therapy were randomized at a ratio of 1:1:1:1 to receive oral Orelabrutinib at 50 mg, 80 mg, 100 mg dosages or placebo once daily, for 12 consecutive weeks.

The Phase II results showed that Orelabrutinib was safe and well tolerated at all doses. A dose dependent efficacy was observed in evaluable patients treated with Orelabrutinib. The SRI-4 response rates at 12-week were 35.7%, 50.0%, 61.5% and 64.3% in patients treated with placebo, 50 mg/day, 80 mg/day and 100 mg/day of Orelabrutinib, respectively. Treatment with Orelabrutinib led to a reduction in levels of proteinuria, and improvement of immunologic markers, including reduced immunoglobulin G and increased complements C3 and C4.

Based on the Phase IIa results, we entered the next stage of clinical development of Orelabrutinib in SLE at the end of 2022. This is a randomized, double-blind, placebo-controlled, multicenter, Phase IIb study evaluating the efficacy and safety of Orelabrutinib in adult patients with SLE. The purpose of the trial is to evaluate the efficacy of Orelabrutinib in SLE subjects and evaluate the safety, tolerability, and impact on the quality of life of subjects with moderate to severe SLE. The patients receiving standard therapy were randomized at a ratio of 1:1:1 to receive oral Orelabrutinib at 25 mg, 50 mg, or placebo once daily, for 48 consecutive weeks. The primary endpoint will focus on the SRI-4 response rate with other secondary points including but not limited to SRI-6 response rate, changing from baseline in complement C3, complement C4, and anti-dsNDA antibody levels, etc.



SLE is a complex and challenging disease for drug development. With regard to the two BTK inhibitors reported clinical results (evobrutinib and fenebrutinib), no significant impact on the disease progression was observed (*Ringheim, G. E., Wampole, M., & Oberoi, K. (2021) Frontiers in immunology, 12, 662223*). Orelabrutinib has the potential to become the first BTK inhibitor that controls the disease activity in SLE patients, and its oral administration should have obvious advantages over commonly used injectable SLE drugs.

Orelabrutinib for ITP

ITP, also referred to as immune thrombocytopenic purpura, is an acquired immune mediated disorder characterized by a decrease in peripheral blood platelet counts, resulting in an increased risk of bruising and bleeding. The main pathogenesis of ITP is the loss of immune tolerance to platelet auto-antigens. This immune intolerance leads to increased platelet destruction and decreased platelet production from megakaryocytes by autoantibodies and cytotoxic T lymphocytes.

BTK is a key kinase in the B cell receptor signaling pathway, which is essential for the activation of B lymphocytes, macrophages, and other immune cells as well as the production of antibodies in the pathological process of ITP. No BTK inhibitor has been approved for the treatment of patients with ITP in the world. Orelabrutinib, with its high target selectivity and good safety profile, has the potential to become a novel treatment option to ITP patients.

Current Status

We entered Phase II clinical trial of Orelabrutinib for the treatment of ITP in mainland China in 2022. This is a randomized, multicenter, Phase II study to evaluate the efficacy and safety of Orelabrutinib in adult patients with persistent or chronic primary ITP and provide a basis for Phase III study design including the dose selection. The primary endpoint will be concentrated on the proportion of subjects with platelet count $50 \times 10^9/L$ (platelet count should be detected at least twice consecutively, with an interval of at least 7 days).

As of cut-off date on 6 February 2023, the data from 22 patients with previous response to glucocorticoids (“GC”) or intravenous immunoglobulin (“IVIG”) were analyzed: 75.0% (6 out of 8) patients at the 50 mg arm achieved the primary endpoint. For the overall population, 36.4% (12 out of 33) patients met the primary endpoint, while 40% (6 out of 15) from the 50 mg arm.

The Phase II favorable data demonstrated proof of concept of Orelabrutinib in ITP and provided us certain confidence to move the project forward.

Orelabrutinib for NMOSD

NMOSD is a chronic inflammatory demyelinating autoimmune disease of the central nervous system mainly involving the optic nerve and spinal cord, which are mediated by antigen-antibodies related to humoral immunity. Clinically, it is characterized by attacks of predominantly optic neuritis and longitudinally extensive transverse myelitis. One latest Chinese epidemiological study based on inpatients shows that the peak incidence of the disease is 45-65 years old, the incidence rate is 0.445/100,000 people per year, and the ratio of female to male is 4.71:1.

The etiology and pathogenesis of NMOSD is considered to be related to a specific aquaporin 4 antibody (“AQP4 IgG”) produced by mature B cells, and up to 80% of patients are serologically AQP4 IgG positive. BTK is a key kinase in B cell receptor signal transduction pathway, which is responsible for regulating B cell proliferation, differentiation, maturation and cytokine expression. Abnormal activation of BTK related signaling pathway can lead to autoantibody production and autoimmune diseases. Thus, BTK inhibitors, especially a brain penetrant BTK inhibitor such as Orelabrutinib hold high potential to become a novel therapy for NMOSD.

Current Status

As of the date of this announcement, one investigator initiated (“IIT”) Phase II trial is ongoing, and we plan to initiate InnoCare sponsored trial when we obtain the primary results.

T Cell Pathway – TYK2 for Autoimmune Diseases

ICP-332

ICP-332 is a small molecule inhibitor of TYK2 that is developed for the treatment of various autoimmune disorders. TYK2 is a member of the JAK family and plays a critical role in transducing signals downstream of IL-12/IL-23 family interleukin receptors as well as type I interferon (“IFN”) receptor. These cytokine/receptor pathways drive the functions of T helper 17 (“TH17”), TH1, B and myeloid cells which are critical in the pathobiology of multiple autoimmune and chronic inflammatory diseases including psoriasis, psoriatic arthritis, inflammatory bowel disease, lupus, AD, and etc. ICP-332 was designed to be a potent and selective TYK2 inhibitor with 400 folds of selectivity against JAK2 to avoid the adverse events associated with nonselective JAK inhibitors. Thus, by selective inhibition of TYK2, ICP-332 may become a potential therapy for multiple autoimmune diseases, such as atopic dermatitis, psoriasis, psoriatic arthritis, systemic lupus erythematosus, IBD, dermatomyositis and uveitis, with better safety profiles.

According to the source of Pharma Intelligence, atopic dermatitis has become a major autoimmune disease with 12 months prevalence in the range of 0.96–22.6% in children and 1.2–17.1% in adults, indicating a global market potential of US\$10 billion in 2030. With tremendous potential to address the massive unmet needs in the above-mentioned indications which have millions of patients, we anticipate ICP-332 would become the cornerstone product in our autoimmune franchise.

Current Status

On 18 May 2021, CDE approved Phase I clinical trial of our ICP-332. We completed the first subject dosing on 16 August 2021 and finished the Phase I clinical trial in March 2022. Based on the data of safety, PK/PD, and biomarkers with no significant decrease of platelet and hemoglobin (JAK-2 related AE) in the Phase I study, we initiated Phase II study in AD in China, which is a randomized, double-blind, placebo-controlled, multicenter trial to evaluate the safety, efficacy, pharmacokinetics, and pharmacodynamics in patients with atopic dermatitis.

In early 2022, the randomized dose-escalation Phase I study in healthy subjects was conducted to evaluate the safety, tolerability, PK and PD profiles of ICP-332 following a single dose (5~320 mg) and multiple doses (40~160 mg QD) escalation for 14 consecutive days under fasted condition. In each cohort, 8 subjects were randomized to receive ICP-332 (6 subjects) or placebo (2 subjects). Food effects on the pharmacokinetics of ICP-332 were tested in the 80 mg cohort.

ICP-332 demonstrated dose proportionality of the PK parameters (C_{max} and AUC_{last}) in the range of 5 mg~320 mg. There was no drug accumulation in plasma after repeated dosing. No significant food effect was observed following co-administration with standard high-fat, high-calorie meals. ICP-332 was safe and well tolerated in healthy subjects who received a single dose up to 320 mg or multiple doses up to 160 mg QD for 14 days. The maximum tolerated dose was not reached.

ICP-488

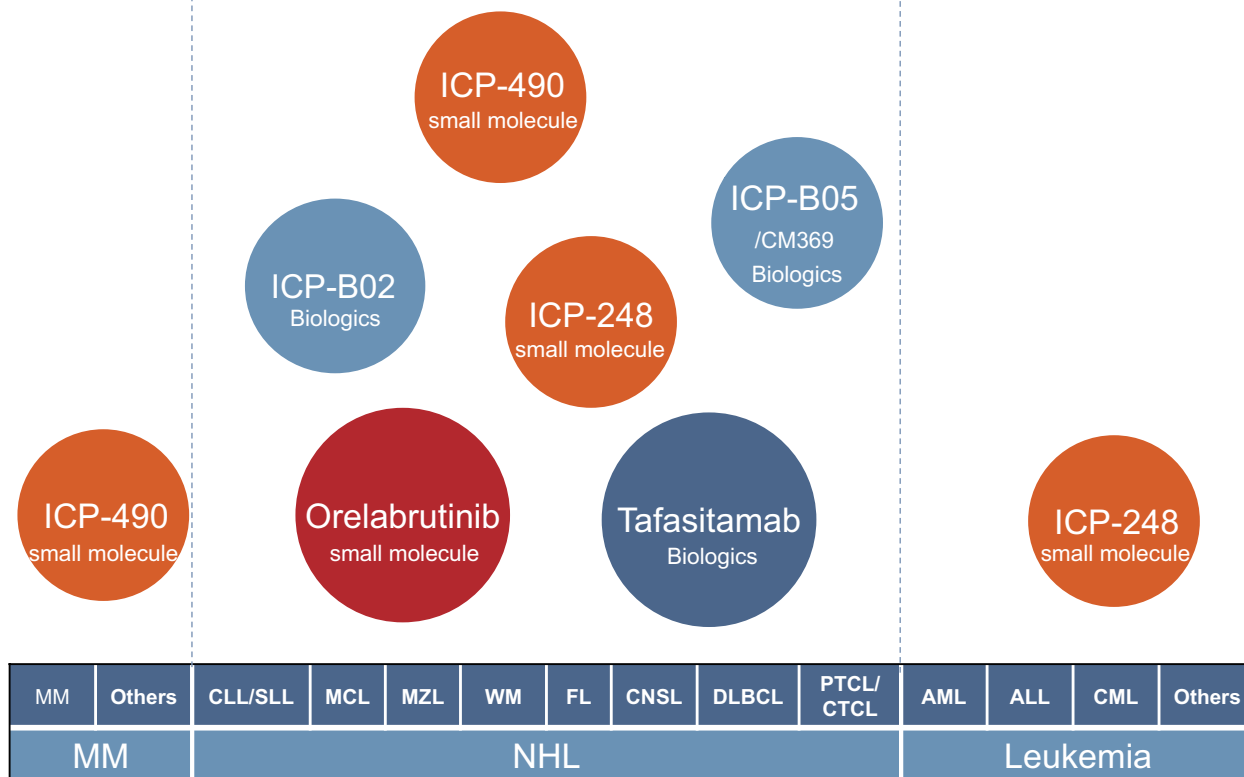
ICP-488 is a small molecule inhibitor of the pseudo kinase domain JH2 of TYK2. JH2 has an important regulatory role in TYK2 kinase catalytical activity, and mutations in JH2 have been shown to be the cause of or be linked with impaired TYK2 activity. ICP-488 is a potent and selective TYK2 allosteric inhibitor that, by binding to the TYK2 JH2 domain, blocks IL-23, IL12, type 1 IFN and other autoimmune cytokine receptors. We intend to develop ICP-488 for the treatment of autoimmune diseases such as psoriasis, psoriatic arthritis, SLE, LN, and IBD, etc. Together with ICP-332, ICP-488 will further enrich our TYK2 portfolio.

The first subject was dosed in August 2022 and the patient's enrollment of the Phase I trial is ongoing in China as of the date of this announcement. The single ascending doses ("**SAD**") part with dose range from 1 mg to 36 mg, two cohorts of multiple ascending doses ("**MAD**") have been completed. Patients with psoriasis will be treated at selected doses. As the date of announcement, ICP-488 is safe and well-tolerated in patients.

BUILDING A LEADING FRANCHISE IN HEMATO-ONCOLOGY

With Orelabrutinib as a backbone therapy and the support of our abundant pipeline in hematology, such as ICP-248, ICP-490, ICP-B02, Tafasitamab and potential future internal and external pipeline development, we aim to become a leading player in hemato-oncology in China and worldwide by covering non-hodgkin lymphoma ("**NHL**"), multiple myeloma ("**MM**"), and leukemia segments by mono or combo therapy. Further, a particular combination therapy toolkit is well designed and aims to position a full coverage of DLBCL.

We are well underway towards building a leading hemato-oncology franchise to cover MM, NHL and leukemia segments with (i) the core internal developed Orelabrutinib as a backbone therapy, (ii) the U.S. FDA and European Medicines Agency ("**EMA**") approved anti-CD19 antibody Tafasitamab for r/r DLBCL, (iii) multiple pipeline drugs that cover almost all important hemato-oncology targets such as CD20xCD3, BCL-2 and E3 ligase, and (iv) a well-established and focused commercialization platform in China. In hema-oncology franchise, we have well defined a differentiated strategy for DLBCL, which is a comprehensive toolkit including the mentioned core product Orelabrutinib, Tafasitamab, BCL-2 and E3 Ligase that offers us a unique position to tackle all stages of all DLBCL patients with combination therapies. Particularly, we pursue to leverage Orelabrutinib for the challenge 1L DLBCL subtype MCD as the initial step and utilize the Tafasitamab plus lenalidomide or additional combination therapy with Orelabrutinib for the r/r DLBCL.



NHL – indolent lymphoma

Orelabrutinib for Hema-oncology Diseases

As of at the date of this announcement, we have dosed over 850 patients across all of our clinical trials of oncology and autoimmune diseases for Orelabrutinib. Besides the NDA approval of r/r CLL/SLL and r/r MCL, we obtained NDAs acceptance for 2 more indications, one of which is under the CDE’s priority review and the other has completed the site inspection. In addition, 5 more registrational trials are ongoing in China and U.S. At the end of 2022, r/r MCL has been approved to be launched in Singapore. The clinical data indicate that Orelabrutinib’s high target selectivity and exceptional target occupancy rate have resulted in favorable safety and efficacy profiles, especially that no severe adverse events (“AEs”) (Grade ≥ 3) of atrial fibrillation case was reported to date.

Orelabrutinib for 1L CLL/SLL

This is a randomized, multicenter, open-label, Phase III study to evaluate the efficacy and safety of Orelabrutinib versus chlorambucil plus rituximab in subjects with previously untreated CLL/SLL. The primary endpoint of this study is progress-free survival (“PFS”) evaluated by the IRC. The study is currently recruiting in 51 sites in China, and more than two third of the subjects were enrolled. Interim analysis is designed for early efficacy readout.

Orelabrutinib for r/r CLL/SLL

This is an open-label, multicenter, Phase II study to evaluate the safety and efficacy following 150 mg daily oral administration of Orelabrutinib in r/r CLL/SLL patients. A total of 80 patients with r/r CLL/SLL were enrolled. According to the data of 30 December 2022, the median follow-up time was 47 months, with 56.2% remaining on treatment. The ORR was 93.8% with 30% complete response (“**CR**”) as assessed by investigator. Median time for achieving first response was 1.84 months. The median duration of response (“**DOR**”) and progression-free survival (“**PFS**”) were not reached. The estimated 48-month DOR and PFS were 56.2% and 52.7%, respectively by investigator assessment. Orelabrutinib showed a significant higher CR rate in r/r CLL/SLL in comparison with other BTK inhibitors at a similar median follow-up period. Long term follow up did not suggest any safety signal other than the ones observed previously. Similar to the previously reported safety results, most AEs were mild to moderate.

In the U.S., we are evaluating the efficacy and safety of Orelabrutinib for the treatment of r/r CLL/SLL. In the second half of 2022’s report, we disclosed that four subjects who had received prior therapies including but not limited to ibrutinib, Gazyva, FCR (Rituximab, Fludarabine, Cyclophosphamide) and lenalidomide, etc. and due to the toxicity or disease progression issues, the prior BTKi treatments were discontinued. The four subjects were treated with Orelabrutinib for a range from 7.16 to 11.07 months. Three of them reached PR/PR-L while the other one reached SD after the 3 cycles treatment. In the evaluable patients, the ORR was 75% while the DCR is 100%, suggesting Orelabrutinib is effective and tolerable in prior BTKi intolerant or relapsed CLL/CLL patients.

Orelabrutinib for 1L MCL

This is a randomized, open-label, multicenter, Phase III study of Orelabrutinib in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (“**R-CHOP**”) vs. R-CHOP in patients with treatment-naïve mantle cell lymphoma. The primary endpoint is PFS evaluated by the IRC according to the 2014 International Working Group Criteria for Non-Hodgkin Lymphoma (“**iwNHL**”). As of the date of this announcement, the study is recruiting patients in 22 active sites in China.

Orelabrutinib for r/r MCL

A Phase II open-label, multicenter, the study was conducted to evaluate the long-term safety and efficacy of Orelabrutinib as a monotherapy for r/r MCL. The primary endpoint was ORR assessed per Lugano criteria. Safety and other efficacy (DOR, PFS, OS) evaluations were chosen as secondary endpoints. A total of 106 patients were enrolled with a median follow up time of 39.43 months.

The efficacy results were evaluated by investigators. According to the protocol analysis, among the 106 patients, 83% ORR and 87.8% disease control rate were achieved. The CR-rate was 36.8% when measured with the conventional computerized tomography (“**CT**”) method.

For Orelabrutinib safety profile in r/r MCL patients, the frequently reported treatment related adverse events (“**TRAEs**”) were primarily hematological toxicities including thrombocytopenia, neutropenia, leukopenia, and hypertension. The most frequently reported AEs (Grade ≥ 3) of any cause was thrombocytopenia. These results suggested that safety events primarily occurred during early stage of treatment and appeared less frequently with continued Orelabrutinib treatment.

In the U.S., enrollment for global Phase II registrational trial for r/r MCL was completed. Orelabrutinib has been granted breakthrough therapy designation (“**BTD**”) by FDA and will take accelerated development path in the U.S. We have demonstrated similar efficacy and safety profile for Orelabrutinib in r/r MCL patients from US, China and other countries.

Orelabrutinib for r/r WM

WM is a B-cell disorder characterized primarily by bone marrow infiltration with lymphoplasmacytic cells, along with immunoglobulin M (“**IgM**”) monoclonal gammopathy. BTK plays a key role in signaling pathways for the survival of WM clone, particular in patients harboring MYD88L265P mutations. However, due to target selectivity issue, clinical uses of marketed BTK inhibitors are compromised with off-target activities to many other kinases besides BTK.

This study aims to evaluate the efficacy and safety of Orelabrutinib for the treatment of r/r WM patients. The primary endpoint was major response rate (“**MRR**”) as assessed by IRC. Key secondary endpoints were MRR as assessed by investigator, ORR, DOMR, PFS, OS, etc. Favorable safety and efficacy results were achieved for this trial:

With a median duration of treatment of 24.90 months, MRR was 80.9% as assessed by investigator. ORR was 91.5%. The estimated 12-month DOMR was 84.9%. The estimated 12-month PFS was 81.2%. The median PFS has not been reached. The most commonly reported adverse events (“**AEs**”) were thrombocytopenia, neutropenia, leukopenia, upper respiratory infection. There was no reported Grade 3 or higher atrial fibrillation and/or atrial flutter, or Grade 3 diarrhea. The study result was published at Lancet eClinicalmedicine in 2022.

Orelabrutinib for r/r MZL

This is a phase II, multicenter, open-label study to evaluate the safety and efficacy of Orelabrutinib 150 mg daily in patients with r/r MZL. As of October 8, 2022, 111 subjects have been treated with Orelabrutinib, of whom 90 subjects were confirmed with MZL by central pathological review. Among the 90 subjects with r/r MZL, 53 patients achieved remissions (PR:43; CR:10), and the ORR was 58.9% (95%CI: 48.0, 69.2) assessed by independent review committee (“**IRC**”). All reached the pre-set primary endpoints. The median duration of response (“**DOR**”) was 34.3 months (95% CI: NA, NA). The median progression-free survival (“**PFS**”) and overall survival (“**OS**”) were not reached. The estimated 12-month PFS and OS were 82.8% and 91%, respectively by IRC assessment. Orelabrutinib showed higher ORR, CR rate and estimated PFS and OS rates in r/r MZL compared with ibrutinib at a similar median follow-up period.

The priority review was granted by CDE to the study in 2022. The NDA is under CDE’s review. Orelabrutinib is the first BTK inhibitor to apply the r/r MZL indication in China. It is expected to be approved in the first half of 2023.

NHL – aggressive lymphoma/DLBCL

Orelabrutinib for 1L DLBCL-MCD Subtype

We have clearly defined our differentiated strategy for DLBCL, the largest subtype of NHL with more than 1 million patients in the worldwide and initiated our challenge to 1L DLBCL by selecting MCD subtypes. This is a Phase III, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of Orelabrutinib plus R-CHOP versus placebo plus R-CHOP in treatment-naive patients with MCD subtype DLBCL. The primary endpoint is PFS accessed by IRC. The study is currently recruiting in 45 sites in China.

Approximately 40% DLBCL patients will eventually become refractory/relapsed. To that, the heterogeneous genetic aberration background is considered one of the underlying reasons. Recent research has been more supportive that R-CHOP+X with genetic rationale will probably provide synergy between multiple novel agents. Among the already classified genetic subtypes, MCD is predominantly enriched with B-cell receptor-dependent NF-KB activation which indicates this patient sub-group might respond well to BTK inhibitors. The pre-clinical model has also demonstrated that Orelabrutinib preserves NK-cell-mediated antibody-dependent cell-mediated cytotoxicity (“ADCC”) induced by anti-CD20 antibody due to less inducible T cell kinase (“ITK”) inhibition. Improved safety profile due to high kinase selectivity also made Orelabrutinib a better candidate in combination therapies. These findings provide a reasonable basis for us to explore the combination of Orelabrutinib and R-CHOP to improve treatment outcome of MCD subtype DLBCL.

The real-world data regarding Orelabrutinib in combination with R-CHOP for MCD DLBCL were posted at American Society of Clinical Oncology (“ASCO”) in June 2022. Fourteen patients with MCD DLBCL were included in the study. All patients received Orelabrutinib 150 mg once daily. Among them, 8 were treated with R-CHOP or R-EPOCH as first-line therapy, and 6 with RICE, R-CHOP or R2 as second line therapy. The complete response rate (“CRR”) for the first-line and second-line patients were 75% and 66.67%, respectively. Reported AEs were generally manageable and resolved soon after supportive treatment. The preliminary conclusion is that Orelabrutinib containing regimens demonstrated encouraging efficacy and well-tolerated safety profile among patients with MCD subtype DLBCL. A large-scale prospective registrational clinical study is in progress, which could offer a new potential therapeutic option for patients with MCD subtype DLBCL.

Further, a comprehensive toolkit including Orelabrutinib, Tafasitamab (CD19), ICP-B02 (CD3xCD20) and, ICP-490 (E3 Ligase) offers us a unique position to tackle all stages of DLBCL patients with combination therapies. More details of the relevant clinical trials will be narrated in the following pipeline’s progress.

Orelabrutinib for Relapsed/Refractory Primary Central Nervous System Lymphoma (“r/r pCNSL”)

The survival outcomes of patients with r/r pCNSL remain extremely poor and there are no approved therapies or widely accepted “standard-of-care” approaches. Eight investigator-initiated studies published the results in 2022, showing promising data of Orelabrutinib-based regimens on the newly diagnosed pCNSL (“ND pCNSL”) and r/r CNSL. The ORR and CR rate of Orelabrutinib combined with immunochemotherapy was 88.9% to 100% and 53.9% to 61.8% in patients with newly diagnosed pCNSL, respectively. The vast majority of the patients with ND pCNSL responded well to the combinations of Orelabrutinib and traditional immunochemotherapy with more than half achieving complete remission. The median PFS (“mPFS”) was not achieved in these studies with a 6-month PFS rate of 63.6% to 100%.

In the relapse/refractory setting, approximately 60% of patients with r/r CNSL achieved remission with an ORR of 60% to 86.7%, and most of those responders achieved complete remission. The mPFS was 9.8 months which was a significant improvement from the historical mPFS of around 3 months.

The patients with enhanced BCR signaling, especially the MYD88 mutation, exhibited superior response, which was consistent with the MOA of Orelabrutinib. Orelabrutinib had such excellent blood-brain barrier (“**BBB**”) permeability that 150 mg orally per day led to a median cerebrospinal fluid concentration of 21.6ng/mL and a median BBB permeability rate of 58.6%.

Orelabrutinib combined with immunochemotherapy was tolerable and manageable. The safety profile observed in these studies was consistent with the results in previous clinical trials. No new safety signal has been observed in pCNSL patients so far.

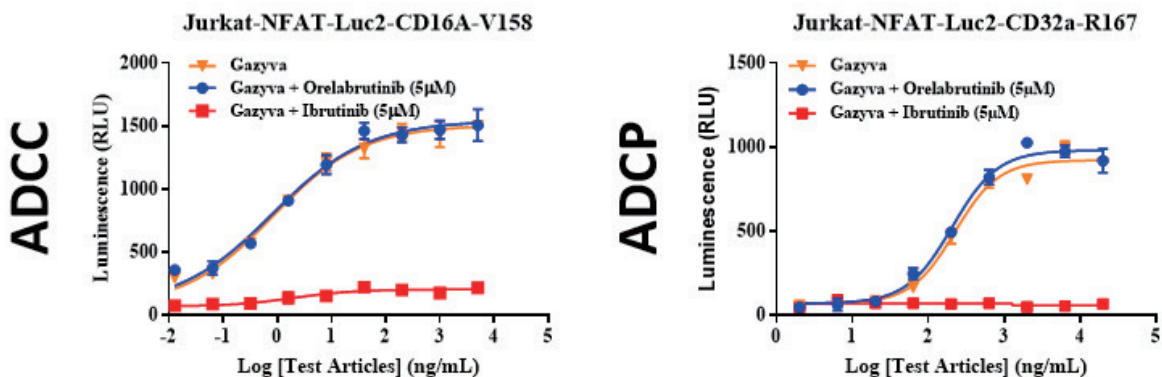
Orelabrutinib Combination Therapies

The scientific rationales of the combination of BTK inhibitor with anti-CD20 antibody would need each agent not only to work through its distinct mechanisms of action and enhance tumor eradication, i.e., for BTK inhibitor to disrupt B-cell receptor (“**BCR**”) proliferative and pro survival signals, and for anti-CD20 antibody to tackle tumors cells through complement-dependent cytotoxicity (“**CDC**”), ADCC/ADCP, and direct apoptosis induction; but also to avoid significant antagonisms of the combo partners. However, the off-target inhibition of BTK inhibitor on interleukin-2 (“**IL-2**”)-ITK may lead to compromised effector activity of NK cells and thus reduced ADCC function of rituximab and much-muted efficacy of combination therapies (Mol Ther Oncolytics 21:158-170; 2021).

Orelabrutinib, a novel BTK inhibitor, was designed with high selectivity to BTK. A recent study has demonstrated in several B-cell tumor models that Orelabrutinib in combination with rituximab can well preserve or slightly enhance the ADCC function of rituximab and lead to robust in vitro and in vivo tumor-killing efficacy (Mol Ther Oncolytics 21:158-170; 2021). Our in-house data have also shown that Gazyva, retain fully functional ADCC and antibody-dependent cellular phagocytosis (“**ADCP**”), activities when combined with Orelabrutinib. Interestingly, similar observations have been made not only in anti-CD20 antibody combinations but also in anti-CD19 antibody Tafasitamab combinations.

BTKi + Gazyva (Obinutuzumab)

(Reporter assays: TMD8 as target cell)



The above chart demonstrated the ADCC and ADCP activities of anti-CD20 antibody Gazyva (obinutuzumab) are well retained by Orelabrutinib, but significantly suppressed by ibrutinib.

Collectively, highly selective BTK inhibitor Orelabrutinib represents a potentially best-in-class combo partner for antibody combination therapies. We believe that Orelabrutinib and anti-CD20/anti-CD19 antibody combinations would benefit patients with B cell lymphoma, especially those with relapsed or refractory diseases.

We are exploring the combinational therapy of Orelabrutinib with Gazyva, an anti-CD20 antibody, for the treatment of B cell lymphoma. We are also proceeding the combination therapy of Orelabrutinib with Tafasitamab/Lenalidomide Phase II clinical trial in China for the potential treatment for NHL.

ICP-B04 (Tafasitamab)

The 2022 CSCO Guidelines were officially released in the first half of 2022. Tafasitamab in combination with Lenalidomide was officially included as a class II recommended regimen for the treatment of adult patients with r/r DLBCL who are ineligible for ASCT. The Guidelines further explains that patients with r/r DLBCL are recommended to choose other drugs that do not have cross-resistance with CHOP, that is, second-line regimens or individualized regimens.

We obtained approval of the Health Commission and Medical Product Administration of Hainan Province under the early access program in Boao Lecheng International Medical Tourism Pilot Zone. On 22 July 2022, this first prescription of Tafasitamab in combination with lenalidomide was issued under Boao Hope City's early access program. This prescription marks the first application of Tafasitamab in patients in China. Tafasitamab, in combination with lenalidomide is not approved by the National Medical Products Administration (NMPA) for any indication in China, except that the combination has been approved for urgent clinical use in Hainan Province of mainland China and the first patient reached CR after 2 cycles of treatment. In addition, the combination therapy was approved by the Department of Health in Hong Kong in December 2022, and we plan to apply for the prior use in the Greater Bay Area of mainland China. As of the date of this announcement, Tafasitamab has been included in the overseas special drug list by 18 provinces and cities in mainland China including Shanghai, Hebei, Hainan provinces, and Suzhou city, etc., which improves the accessibility of Tafasitamab to the patients with DLBCL.

The Phase II pivotal trial of Tafasitamab and Lenalidomide combo therapy for the treatment of r/r DLBCL is ongoing to support the approval in mainland China. This is a single-arm, open-label, multicenter Phase II clinical study evaluating the safety and efficacy of Tafasitamab combined with Lenalidomide in the treatment of patients with r/r DLBCL. The primary endpoint is to evaluate the ORR and the evaluation will be conducted by IRC. The secondary endpoints are DCR, DoR, PFS, time to progression (“**TTP**”), time to response (“**TTR**”), OS and safety, etc. As of the date of this announcement, the recruitment is ongoing in 24 active cities in mainland China. The first patient was enrolled in September 2022, and we endeavor to speed up the patient's enrollment in 2023.

Tafasitamab offers the possibility and flexibility in combination with Orelabrutinib and our other assets for the treatment of B-cell malignancies. DLBCL, which is the largest subtype, takes up approximately 40% of NHL patients. According to Frost & Sullivan report, it is estimated that DLBCL market would probably be able to expand from US\$5.9 billion in 2023 to US\$11.9 billion in 2023. For example, we are exploring synergistic combination to target NHL/DLBCL with Tafasitamab and Lenalidomide and Orelabrutinib in mainland China.

In the second half of 2021, we entered into a collaboration and license agreement with Incyte for the development and commercialization of Tafasitamab, a humanized Fc-modified cytolytic CD19 targeted immunotherapy, in Greater China. Tafasitamab in combination with lenalidomide is approved by the U.S. FDA and European Medicine Agency for the treatment of adult patients with r/r DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for ASCT. The accelerated approval in the U.S. is based on the Phase II L-MIND study which showed 57.5% ORR (40% CR) and 33.5 months mOS. The mDoR of 43.9 months indicates a greater and potentially durable benefit. Tafasitamab was the first approved second-line treatment in the U.S. for this patient population. With a similar role and more stable expression cross B-NHL, this CD19 targeted immunotherapy has the potential to become another fundamental therapy for B-NHL. In RE-MIND2 trial, a retrospective cohort analysis, Tafasitamab plus lenalidomide demonstrated significant improvement in overall survival and objective response rate compared to R2 regimen.

We paid Incyte US\$35 million upfront fee and Incyte is eligible to receive up to an additional US\$82.5 million in potential development, regulatory and commercial milestones, as well as tiered royalties. Under the said collaboration and license agreement, we were granted the right to develop and exclusively commercialize Tafasitamab in the field of hematology and oncology in mainland China, Hong Kong, Macau and Taiwan.

The strategic collaboration with Incyte will not only enhance our strength in the field of hematology and oncology, but also offers us a good opportunity to explore the potential clinical benefit of our BTK inhibitor Orelabrutinib in combination with Tafasitamab. Tafasitamab is being investigated as a therapeutic option in B-cell malignancies in a number of on-going combination trials. In addition, we believe that Tafasitamab, which mediates B-cell lysis through apoptosis and immune effector mechanism including ADCC and ADCP, an innovative and differentiated CD19 targeted immunotherapy, is critical to solidifying our long-term strategy of developing a leading hematology oncology franchise.

For a detailed overview of the said strategic collaboration with Incyte and detailed mechanism of Tafasitamab, please see our announcement dated 17 August 2021 published on the website of the Stock Exchange and the Company.

ICP-B02 (CM355)

ICP-B02 is a CD20xCD3 bispecific antibody co-developed with KeyMed for the treatment of lymphoma as monotherapy or in combination with other therapies. In preclinical studies, it demonstrated stronger TDCC activities with less cytokine release as compared to its leading competitors. The development of ICP-B02 is based on our collaboration with KeyMed via a 50:50 joint venture that was formed in August 2018 for the discovery, development, and commercialization of biologic drugs. In June 2020, we entered into a license and collaboration agreement, under which KeyMed granted us an exclusive license for 50% ownership of ICP-B02.

We are conducting a phase I/II clinical trial in China to assess the safety, tolerability, PK, and the preliminary anti-tumor activity of ICP-B02 in r/r NHL. In the Phase I dose escalation study, ICP-B02 was administered intravenously with step-up doses. We have completed the DLT evaluation for the 1st four dose groups, which accelerated titration design was applied to. Currently, the enrollment of the 5th dose group was ongoing, starting from which 3+3 method will be followed. So far, there was no DLTs observed, while almost complete B cell depletion was achieved in patients treated with low dose of ICP-B02. The IND application for ICP-B02 subcutaneous (“SC”) formulation was approved by the CDE in March 2023.

Multiple Myeloma (“MM”)

ICP-490

ICP-490 is a proprietary, orally available, next generation CRBN E3 Ligase modulator that modulates the immune system and other biological targets through targeted protein degradation (“TPD”).

By specifically binding to CRL4CRBN-E3 Ligase complex, it induces ubiquitination and degradation of transcription factors including IKZF1 (“**Ikaros**”) and IKZF3 (“**Aiolos**”). ICP-490 is much more potent than competitor investigational CRBN E3 Ligase modulator and is able to induce a swift and deep degradation of transcription factors Aiolos and Ikaros at sub-nanomolar concentrations. In the in vivo efficacy studies, ICP-490 demonstrated significant anti-tumor effects in various multiple myeloma (“MM”) and diffuse large B cell lymphoma (“DLBCL”) xenograft models. It overcomes acquired resistance against earlier generations of CRNB modulators in both in vitro and in vivo preclinical studies. In addition, ICP-490 synergizes with anti-CD38 antibody daratumumab in preclinical assays by enhancing its ADCC activity, thus provides scientific rationales for combinatory treatment in clinic.

As a molecular glue protein degrader, clinically, ICP-490 may be used for the treatment of patients with multiple myeloma, DLBCL and other non-Hodgkin lymphomas as monotherapy or in combination with other therapies autoimmune diseases such as systemic lupus erythematosus. ICP-490 has immense potential in hemato-oncology field, including displacing current IMiDs in early-line treatments for MM and combining broadly with existing stand-of-care therapies for the treatment of both MM and NHLs.

The IND application for oncology indications was approved by the CDE in July 2022 and the Phase I dose escalation study is ongoing.

Leukemia

ICP-248

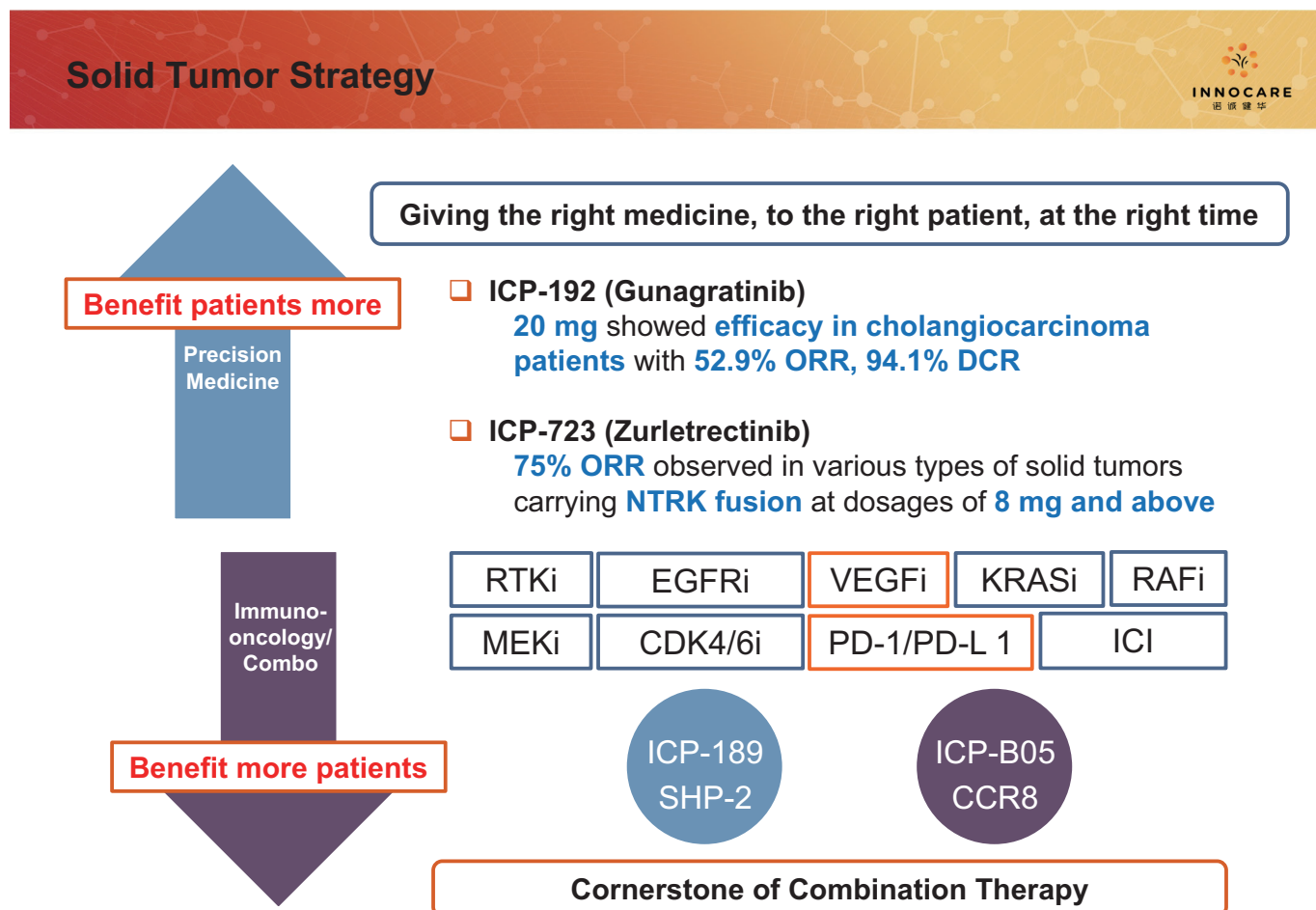
ICP-248 is a novel, orally bioavailable B-cell lymphoma-2 (“**BCL-2**”) selective inhibitor. BCL-2 is an important part of apoptotic pathway and is overexpressed in a variety of hematologic malignancies. BCL-2 inhibitors have shown anti-tumor effects by activating the endogenous mitochondrial apoptosis pathway that causes rapid cancer cell apoptosis. However, as resistance to existing BCL-2 inhibitors is nearly inevitable, the optimal clinical treatment will be to use them in combination with other treatments. By increasing metabolic stability and reducing impact on liver drug enzymes, we have developed ICP-248 to be more suitable for combinational therapies. Given the outstanding safety and efficacy profile of Orelabrutinib, we are confident that the combination of ICP-248 and Orelabrutinib will overcome resistance seen in existing BCL-2 inhibitors. We intend to develop ICP-248 in combination with Orelabrutinib for the treatment of acute lymphoblastic leukemia (“**ALL**”), acute myeloid leukemia (“**AML**”), follicular lymphoma (“**FL**”), CLL, DLBCL and other hematological malignancies. Since BCL-2 inhibitor’s market grew by 10% in 2022 to more than US\$2 billion, we expect ICP-248 would have extraordinary blockbuster potential.

The IND application for ICP-248 was approved by the CDE in September 2022 and we have entered the Phase I trial in the end of 2022. This is an open-label, multicenter, Phase 1 dose escalation and dose expansion study to evaluate the safety and preliminary efficacy of ICP-248 in r/r B-cell malignancies in China, mainly including r/r CLL/SLL and r/r MCL. The leading site of ICP-248 has been activated. The study result would support ICP-248 combo with Orelabrutinib in the CLL/SLL frontline development. As of the date of this announcement, the first patient was enrolled.

BUILDING A COMPETITIVE DRUG PORTFOLIO FOR SOLID TUMOR TREATMENT IN CHINA AND WORLDWIDE

To benefit patients more, we strived to expanding the breadth of our pipeline covering solid tumor diseases areas through the precision medicine philosophy and intend to provide the right medicine to the right patient at the right time. We believe the potential best-in-class molecules ICP-192 and ICP-723 will enable us to establish a solid initial presence in the field of solid tumor treatment.

To benefit more patients, our rapidly maturing early-stage pipeline including the cornerstone therapy ICP-189 and ICP-B05, and ICP-033 of immune-oncology and tumor driver genes treatments should enable us to provide a competitive treatment solution for a large array of solid tumors for both China and global patients.



Precision medicine, sometimes known as “personalized medicine” is an innovative approach to tailoring disease prevention and treatment that takes into account differences in people’s genes, environments, and lifestyles. For the vision and mission of “benefiting patients more” via precision medicine and “benefiting more patients” via immunology-oncology platform, in the solid tumor field, we believe our potential best-in-class molecules ICP-192 targeting FGFR and ICP-723

targeting pan-TRK will enable us to establish a solid presence therein, while our rapidly growing and maturing cornerstone of combination therapy that builds on ICP-189 and ICP-B05 for targeting novel targets such as SHP2 and CCR8 with additional early-stage pipeline including but not limited to ICP-033 should enable us to provide a competitive treatment solution for a large array of solid tumors for both China and global patients in the future.

ICP-192 (Gunagratinib)

Gunagratinib is a potent and highly selective pan-fibroblast growth factor receptors (“**pan-FGFR**”) inhibitor that we are developing for the treatment of various types of solid tumors. Studies have shown that mutations and aberrant activation of FGFRs are implicated with the development of various cancers, including bile duct, breast, lung, head and neck, gastric and urothelial cancers, accounting for approximately 7.1% of solid tumors.

For a detailed overview of the Mechanism of Action of a pan-FGFR inhibitor, please see our Prospectus.

Current Status

Gunagratinib is a novel pan-FGFR inhibitor that potently and selectively inhibits FGFR activities irreversibly by covalent binding. Preclinical data showed that Gunagratinib overcomes the acquired resistance to the first generation reversible FGFR inhibitors, e.g., infigratinib.

In the middle of January 2023, we presented the ICP-192 data from an ongoing Phase IIa dose-expansion study of Gunagratinib in patients with cholangiocarcinoma (“**CCA**”). 18 CCA patients were enrolled, and 17 patients had at least one tumor assessment. The Median follow-up was 5.57 months. The ORR was 52.9% (9 out of 17) and the DCR was 94.1% (16 out of 17). The median progression free survival (“**mPFS**”) was 6.93 months (95% CI, 5.42-not reached) (not mature at cutoff). No patient discontinued treatment due to TRAE and there was no treatment-related death. Thus, Gunagratinib is safe and well-tolerated with high response rate (52.9%) compared to other approved FGFR inhibitors in previously treated patients with locally advanced or metastatic CCA harboring FGR2 gene fusions or rearrangements.

Gunagratinib is currently undergoing several Phase I/II clinical studies in China, the U.S, and Australia. We entered registrational trial in cholangiocarcinoma in China at the end of 2022 and the Phase II trial in urothelial cancer in China is still progressing. The primary analysis showed the ORR was 44.4% (4 out of 9) and the DCR was 88.9% (8 out of 9) in treatment of urothelial cancer phase II trial. Besides, we are also conducting a basket trial including gastric and head and neck cancer in China, Australia, and the U.S.

ICP-723 (Zurletrectinib)

ICP-723 is a second-generation small molecule pan-inhibitor of tropomyosin-related kinase (“**pan-TRK inhibitor**”) designed to treat patients with NTRK gene fusion-positive cancers who were TRK inhibitor treatment-naïve or who have developed resistance to the first generation TRK inhibitors, regardless of cancer types. First generation pan-TRK inhibitors have shown rapid and durable responses in patients with TRK gene fusions, however, can develop acquired resistance. Preclinical data showed that ICP-723 markedly inhibited the activity of the wild type TRKA/B/C as well as mutant TRKA with resistant mutation G595R or G667C. This finding provides strong evidence that ICP-723 could overcome acquired resistance to the first generation TRK inhibitors. ICP-723 also potently inhibits ROS1 activity and ROS1 fusion-driven tumor growth which was demonstrated in both in vitro cellular assay and in vivo animal model studies.

Mechanism of Action

The TRK family consists of three proteins referred to as TRKA, TRKB and TRKC, respectively, which are encoded by neurotrophic receptor tyrosine kinase genes NTRK1, NTRK2 and NTRK3, respectively. TRKs play an important role in maintaining normal nervous system function. Unwanted joining of separated NTRK genes, or NTRK gene fusions, have been found to contribute to tumorigenesis in a variety of different cancers, with high prevalence in infantile fibrosarcoma, salivary gland carcinomas and thyroid carcinoma. NTRK fusions have also been detected at lower frequencies, in soft-tissue sarcomas, thyroid cancer, mammary analogue secretory carcinoma of salivary glands, lung cancer, colorectal cancer, melanoma, breast cancer, etc. C-Ros Oncogene 1 (ROS1) is a receptor tyrosine kinase that has been shown to undergo genetic rearrangement in a variety of human cancers at variable frequencies. ROS1 fusion-positive NSCLCs are the most common of these cancers in terms of the absolute number of patients given the high incidence of NSCLCs relative to that of other malignancies.

Current Status

We are currently conducting a Phase I/II clinical trial in China to assess the safety, tolerability, and PK, the preliminary anti-tumor activity of ICP-723 in adult and adolescent patients with advanced solid tumor harboring NTRK/ROS1 gene fusion. In June at 2022 ASCO, we reported detailed information about this trial. This is a multicenter, open-label Phase I/II clinical trial, which includes a Phase I dose escalation part and a Phase II dose expansion part. In the Phase I dose escalation, patients with advanced solid tumor, who failed from clinical standard of care or for whom there was currently no effective therapy, were enrolled. The Phase II expansion is conducted in patients with NTRK fusion positive or ROS1 fusion positive, including who developed acquired resistance to first-generation TRK or ROS1 inhibitors.

In the Phase I dose escalation study, dosage has been escalated up to 24 mg with no DLT observed. The Phase II dose expansion study is ongoing with RP2D being determined as 8 mg in preliminary. As of 30 December 2022, 75% ORR (9 PR in 12 patients) was observed in adult patients with various cancers carrying NTRK fusion at different dosages, among which 77.8% ORR (7 PR in 9 patients) was observed at 8 mg. Among the 6 evaluable patients with ROS1 fusion, the ORR was 50%. Most subjects achieved response at the first tumor assessment. In the adolescent arm, there was one subject enrolled at the dosage of 4 mg, who achieved confirmed PR with no DLT observed.

The IND submission for additional pediatric population (<12 years old) was accepted by CDE in January 2023. Further, we submitted EoP2 communication with CDE to initiate registrational trial in January 2023.

ICP-189

ICP-189 is a potent oral allosteric inhibitor of SHP2 with reliable selectivity over other phosphatases. It is being developed for the treatment of solid tumors as a potential cornerstone therapy in combinations with other antitumor agents. SHP2 is a key upstream regulator of the RAS–MAPK pathway and thus plays an essential role in the signaling by multiple oncogenic driver kinases, as well as a key signal transducers of PD-1 signaling, making SHP2 inhibitor an ideal partner for combination with multiple targeted and checkpoint therapies.

In preclinical in vivo efficacy studies, ICP-189 demonstrated significant anti-tumor effects in various xenograft models as monotherapy. ICP-189 has also shown preliminary promising activity in combination with a range of targeted therapies and immunotherapies, including inhibitors of EGFR, KRAS, MEK and PD-1, in preclinical studies.

We are conducting a Phase Ia dose escalation study to evaluate the safety, tolerability and pharmacokinetics and preliminary anti-tumor activity of ICP-189 in patients with advanced solid tumors in China. As of 8 February 2023, dosage has been escalated up to 40 mg with no DLT observed. There were no \geq G3 TRAEs and SAEs. Preliminary efficacy was observed in ICP-189 monotherapy. 1 patient with cervical cancer in 20 mg dose cohort achieved confirmed PR. ICP-189 demonstrated favorable PK profile and long half-life. The exposure of ICP-189 is much higher than that of competitors at the same dose level. Multiple ICP-189 combinations, including treatment with third-generation EGFR inhibitor in lung cancer and anti-PD-1 antibody in multiple cancer types, will be explored clinically in the phase Ib trial and the collaborations with potential partners for combination study are under discussion.

As of the date of this announcement, the IND approval of ICP-189 was granted by the FDA for initiating clinical trial in the U.S.

ICP-B05 (CM369)

ICP-B05 is an anti-C-C motif chemokine receptor 8 (“**CCR8**”) monoclonal antibody, a potential first-in-class drug codeveloped by our Company and KeyMed as a monotherapy or in combination with other therapies for the treatment of various cancers. CCR8 has been shown to be selectively overexpressed on immunosuppressive regulatory T cells (“**Tregs**”) in the tumor microenvironment (“**TME**”). ICP-B05 binds to CCR8 on Tregs and eradicates immunosuppressive Tregs through ADCC to augment the anti-tumor immunity in TME while preserving peripheral homeostasis. ICP-B05 has the potential to deliver optimal tumor targeted Treg depletion and be more specific in anti-tumor activity than other immunotherapies and enhance our strength in the field of the solid tumor by synergizing with our existing pipelines.

In August 2022, the IND approval of ICP-B05 was granted by CDE for initiating clinical trial in China. We are conducting a non-randomized, open-label, multicenter, phase I clinical trial to evaluate the safety, tolerability, pharmacokinetic characteristics, and efficacy of ICP-B05 in subjects with advanced liquid and solid tumors. The first patient of the dose escalation study was dosed in February 2023. We will explore the combination of ICP-B05 with other immunotherapies including immune checkpoint inhibitors in various cancer indications after collecting the safety data of monotherapy.

ICP-033

ICP-033 is a multi-kinase inhibitor mainly targeting discoid in domain receptor 1 (“**DDR1**”) and vascular endothelial growth factor receptor (“**VEGFR**”) that inhibits angiogenesis and tumor cell invasion, normalizes abnormal blood vessels, and reverses the immunosuppressive state of the tumor microenvironment. Preclinical studies have shown that ICP-033 exhibits strong anti-tumor effects both in vivo and in vitro. ICP-033 is intended to be used alone or in combination with immunotherapies and other targeted drugs for liver cancer, renal cell carcinoma, colorectal cancer and other solid tumors.

As of the date of this announcement, ICP-033 Phase I trial is ongoing in China.

Beside the above-mentioned three focused therapeutics areas, with a proven record in small molecule R&D, we are establishing our internal biological drug R&D capability through internal and external efforts. We are also actively considering other new drug modalities such as PROTAC, XDC, molecule glue, etc.

The Company cannot guarantee that it will be able to develop, or ultimately market, any of the products in its pipeline success fully, Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

MANUFACTURING

Guangzhou Manufacturing Facility

Our 50,000 m² small molecule in-house Guangzhou manufacturing facility (“**Guangzhou Base**”) complies with GMP requirements of the U.S., Europe, Japan and China, and have an annual production capacity of one billion pills. We have successfully obtained a manufacturing license for the facility.

On 30 June 2022, we received the approval from the China NMPA to begin the production of commercial supply of our self-developed BTK inhibitor, Orelabrutinib at the Guangzhou Base. In August 2022, the first batch of Orelabrutinib manufactured at the Guangzhou small molecule production facility was released to the commercial market.

Improving the solubility of poorly soluble drugs has become a focus and challenge in the research and development of innovative drug formulation. Our Guangzhou Base has built a technical platform to solve such problems, including the establishment of international advanced production lines of spray dried solid dispersion and solid dosage forms, and equipped with three major technology platforms, namely the solubilization preparation technology for poorly soluble drugs, the release preparation technology for oral solid dosage forms and the targeted drug delivery technology, thereby solving the common problems faced by the industry. Our solid dispersion technology is the core technology in the solubilization process, which can accelerate the solubility and dissolution rate of poorly soluble drugs, thus improving the bioavailability of drugs and better catering for the needs of the development and production of new drugs.

Additionally, the progression of second and third phases of constructions are well planned. Currently, we are expanding the construction of the second phase of the facility in Guangzhou site that is designed to house an additional 30,000 m² production area to provide sufficient capacity for our growing and maturing drug pipeline and to support our continued business expansions.

Beijing Manufacturing Facility

We established a large molecules CMC pilot facility which intends entering operation phase for early clinical supplies in Changping, Beijing. Meanwhile, a 70,381 m² land in Beijing next to our Company headquarter inside the Life Science Park was designed to build a landmark R&D center and large molecule production facility. In August 2022, we kicked off the ground-breaking for the construction and expect it to be completed in 2025.

OTHER CORPORATE DEVELOPMENTS

The RMB Shares of the Company have been listed and become available for trading on the STAR Market since 21 September 2022 and successfully raised fund of approximately RMB2,919 million. For details, please refer to the announcement of the Company dated 20 September 2022.

IMPACT OF THE COVID-19 OUTBREAK

Since the outbreak of the novel coronavirus (“**COVID-19**”) in early 2020, the Company has adopted immediate measures to maintain effective and high-quality level of operation. Although we experienced some delays in the patient enrollment process and data entry for certain of our clinical trials in China at the beginning of the COVID-19 pandemic, there has not been any material disruption of our ongoing clinical trials. Since early 2022, the government implemented different levels of COVID-zero policy in different regions in mainland China. We took various adaptive measures, including but not limited to reducing face-to-face meetings by means of telephone or virtual conferences, avoiding unnecessary travels, which resulted in no significant impact on commercialization or sales. Since November 2022, the government started to ease various COVID-19 restrictions, and we have started to ease the afore-mentioned measures since December 2022.

The COVID-19 pandemic has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in the clinical trials. In addition, our supply chain, product sales and business operation has not experienced any material disruption since the outbreak of COVID-19. We have not experienced and currently do not expect any material regulatory delays in respect of our clinical trials or any long-term impact on our operation or deviation from our overall development plans due to the COVID-19 pandemic. We have not experienced any material impact from COVID-19 on the progress, status or filing update of our ongoing research and clinical activities.

EVENTS AFTER THE END OF THE REPORTING PERIOD

In February 2023, Biogen notified the Company of its decision to terminate its license and collaboration agreement with InnoCare for orelabrutinib, an oral small molecule BTK inhibitor for the potential treatment of MS along with the research and development services. Following the termination, the Company will regain all global rights granted to Biogen, including related intellectual property, decision-making regarding research and development, manufacturing, and commercialization, and commercial proceeds generated from orelabrutinib. The Company and Biogen will collaborate to complete the transition within 90 days.

FINANCIAL REVIEW

Revenue

	Year Ended 31 December			
	2022		2021	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Revenue from continuing operations				
Net sales of drugs	566,755	90.6	214,666	20.6
Research and development services	58,649	9.4	52,404	5.0
Business collaboration	–	–	775,963	74.4
Total Revenue	<u>625,404</u>	<u>100.0</u>	<u>1,043,033</u>	<u>100.0</u>

Our revenue decreased from RMB1,043.0 million for the year ended 31 December 2021 to RMB625.4 million for the year ended 31 December 2022. Sales of drugs revenue increased by RMB352.1 million or 164.0% to RMB566.8 million, as compared to the year ended 31 December 2021. Business collaboration revenue decreased from RMB776.0 million for the year ended 31 December 2021 to nil for the year ended 31 December 2022.

Gross Profit and Gross Profit Margin

	Year Ended 31 December			
	2022		2021	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Sales of drugs	471,170	97.8	191,008	19.5
Research and development services	10,837	2.2	10,395	1.1
Business collaboration	–	–	775,963	79.4
	<u>482,007</u>	<u>100.0</u>	<u>977,366</u>	<u>100.0</u>

As a result of the foregoing, our gross profit decreased from RMB977.4 million (gross profit margin: 93.7%) in 2021 to RMB482.0 million (gross profit margin: 77.1%) in 2022.

Segmental Information

Since the Group's revenue and operating losses were mainly from the activities related to research and development in China, and most of the Group's identifiable operating assets and liabilities are located in China, no geographical segment information is presented in accordance with HKFRS 8 Operating Segments.

Other Income and Gains

Our other income and gains decreased from RMB217.9 million for the year ended 31 December 2021 to RMB198.2 million for the year ended 31 December 2022, primarily attributable to (i) foreign exchange gain from RMB57.1 million in 2021 to nil in 2022; (ii) an increase of RMB8.4 million in investment income from the investments in wealth management products from RMB0.07 million in 2021 to RMB8.5 million in 2022; (iii) RMB29.9 million increase in recognized government grants from RMB16.3 million in 2021 to RMB46.2 million in 2022; and (iv) RMB1.8 million increase in the interest income from RMB135.1 million in 2021 to RMB136.9 million in 2022.

Research and Development Expenses

Our research and development costs decreased from RMB721.6 million for the year ended 31 December 2021 to RMB639.1 million for the year ended 31 December 2022, primarily due to the decrease in license-in expense. Other increase in research and development costs were mainly due to continuous advancement of R&D process leading to increasing pre-clinical, clinical trial costs and talent reserve of R&D team.

	Year Ended 31 December			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
License-in and collaborative R&D expenses	2,490	0.4	273,026	37.8
Direct clinical trial and third-party contracting cost	196,826	30.8	167,589	23.2
Employee cost	223,095	34.9	136,923	19.0
Share-based compensation	58,164	9.1	39,428	5.5
Depreciation and amortization	43,083	6.7	21,837	3.0
Others	115,481	18.1	82,781	11.5
Research and development costs	<u>639,139</u>	<u>100.0</u>	<u>721,584</u>	<u>100.0</u>

- (i) RMB270.5 million decrease of license-in and collaborative R&D expenses from RMB273.0 million to RMB2.5 million;
- (ii) RMB29.2 million increase of direct clinical trial and third party contracting cost from RMB167.6 million to RMB196.8 million;
- (iii) RMB86.2 million increase of R&D employees cost from RMB136.9 million to RMB223.1 million;
- (iv) RMB18.8 million increase of share-based compensation from RMB39.4 million to RMB58.2 million;
- (v) RMB21.3 million increase of depreciation and amortisation from RMB21.8 million to RMB43.1 million; and
- (vi) RMB32.7 million increase of other R&D expenses such as trial materials, consumables and energy, etc., from RMB82.8 million to RMB115.5 million.

Administrative Expenses

Our administrative expenses increased from RMB139.8 million for the year ended 31 December 2021 to RMB181.6 million for the year ended 31 December 2022, primarily attributable to (i) an increase in employee expense of our administrative personnel from RMB47.0 million to RMB78.0 million; (ii) an increase in depreciation and amortization from RMB3.6 million to RMB11.3 million mainly caused by addition of the property, plant and equipment and other intangible assets; (iii) the increase of the taxes and surcharges from RMB1.4 million to RMB6.9 million because of more payment of VAT; and (iv) increase of other administrative expenses from RMB9.2 million to RMB15.8 million as the company has grown in size.

	Year Ended 31 December			
	2022		2021	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Employee cost	78,008	43.0	46,964	33.6
Share-based compensation	34,357	18.9	43,017	30.8
Professional fees	35,159	19.4	35,563	25.4
Depreciation and amortisation	11,297	6.2	3,637	2.6
Taxes and surcharges	6,895	3.8	1,392	1.0
Others	15,840	8.7	9,242	6.6
Administrative Expenses	<u>181,556</u>	<u>100.0</u>	<u>139,815</u>	<u>100.0</u>

Selling and Distribution Expenses

Selling and Distribution expenses increased from RMB298.5 million for the year ended 31 December 2021 to RMB438.6 million for the year ended 31 December 2022, primarily attributable to advancing our commercialization of Orelabrutinib, including (i) an increase in market research and market promotion from RMB126.5 million to RMB219.4 million; and (ii) an increase in employee expense of our sales and marketing personnel from RMB100.7 million to RMB143.1 million.

	Year Ended 31 December			
	2022		2021	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Market research and market promotion	219,422	50.0	126,462	42.4
Employee cost	143,105	32.6	100,712	33.7
Share-based compensation	36,956	8.5	43,999	14.7
Others	39,128	8.9	27,290	9.2
Selling and Distribution Expenses	<u>438,611</u>	<u>100.0</u>	<u>298,463</u>	<u>100.0</u>

Other Expenses

Other expenses was mainly the foreign exchange loss, which changed to an unrealized loss of RMB290.6 million for the year ended 31 December 2022 from a gain of RMB57.1 million for the year ended 31 December 2021, due to USD appreciation against RMB when exchanging our overseas company's RMB balance to its functional currency USD.

Fair value changes of convertible loan

Our fair value changes of convertible loan with Guangzhou Kaide changed from a loss of RMB51.0 million for the year ended 31 December 2021 to a gain of RMB3.4 million for the year ended 31 December 2022.

Share of losses of joint ventures

Our share of losses of joint ventures was RMB9.7 million for the year ended 31 December 2022 comparing to RMB0.6 million for the year ended 31 December 2021, primarily due to increase in share of the losses of joint ventures during the period.

Finance Costs

Our finance costs increased from RMB2.6 million for the year ended 31 December 2021 to RMB17.0 million for the year ended 31 December 2022, primarily attributable to increase of discounting interest cost with new additional right-of-use assets and other current liabilities.

Income Tax

Our income tax was nil for the year ended 31 December 2022, compared to that expense of RMB46.6 million for the year ended 31 December 2021, mainly attributable to the decrease of business collaboration.

Analysis of Key Items of Financial Position

Net Current Assets

The following table sets forth our current assets and current liabilities as of the dates indicated:

	As of 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
CURRENT ASSETS		
Trade receivables	127,825	45,273
Prepayments, other receivables and other assets	95,344	116,145
Inventories	65,322	9,918
Financial assets at fair value through profit or loss	313,290	317,059
Cash and bank balances	8,697,927	5,928,716
Total current assets	9,299,708	6,417,111
CURRENT LIABILITIES		
Trade payables	118,597	84,602
Contract liabilities	4,242	6,831
Other payables and accruals	727,552	204,886
Deferred income	7,757	12,647
Lease liabilities	20,112	20,336
Convertible loan	1,197,168	–
Total current liabilities	2,075,428	329,302
NET CURRENT ASSETS	7,224,280	6,087,809

We had net current assets of RMB7,224.3 million as of 31 December 2022, which was primarily attributable to our cash and bank balances of RMB8,697.9 million, trade receivables of RMB127.8 million, prepayments, other receivables and other assets of RMB95.3 million and financial assets at fair value through profit or loss of RMB313.3 million, which was partially offset by other payables and accruals of RMB727.6 million, trade payables of RMB118.6 million and convertible loan of RMB1,197.2 million.

Trade Receivables

Our trade receivables mainly consist of the receivables by selling drugs and other receivables from providing R&D services. An ageing analysis of the trade receivables as at the end of the Reporting Period, based on the invoice date and net of loss allowance, is as follows:

	As of 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	127,822	45,273
3 months to 6 months	3	–
Trade receivables	<u>127,825</u>	<u>45,273</u>

The Group's trading terms with its customers are mainly on credit, except for new customers, where payment in advance is normally required. The credit period is generally one month, extending up to three months for major customers. Each customer has a maximum credit limit. The Group seeks to maintain strict control over its outstanding receivables to minimise credit risk. Overdue balances are reviewed regularly by senior management. In view of the aforementioned and the fact that the Group's trade receivables relate to several diversified customers, there is no significant concentration of credit risk. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

Prepayments, other receivables and other assets

Our prepayments, other receivables and other assets decreased from RMB116.1 million as of 31 December 2021 to RMB95.3 million as of 31 December 2022, primarily due to RMB16.3 million decrease in other assets from RMB16.3 million as of 31 December 2021 to nil as of 31 December 2022 because the listing expense in other assets was settled in 2022 for RMB Share Issue.

	As of 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments	33,557	37,532
Interest receivable	44,987	41,363
Other assets	–	16,340
Value-added tax recoverable	12,147	17,362
Other receivables	4,653	3,548
	<u>95,344</u>	<u>116,145</u>

Financial assets at fair value through profit or loss

Our financial assets at fair value through profit or loss are wealth management products denominated in RMB, measured at fair value and whose changes are included in the current and non current profit or loss, with RMB313.3 million in current assets as of 31 December 2022, compared with RMB317.1 million in current assets and RMB304.7 million in non current assets as of 31 December 2021.

Inventories

As our sales grew and the Guangzhou Base was put into production in 2022, our inventories, which mainly include raw materials, consigned processing material and finished goods, increased from RMB9.9 million as of 31 December 2021 to RMB65.3 million as of 31 December 2022.

Trade Payables

An ageing analysis of the trade payables as at the end of the Reporting Period, based on the invoice date, is as follows:

	As of 31 December	
	2022	2021
	RMB'000	RMB'000
Within 1 year	111,186	84,459
1 year to 2 years	7,335	121
2 years to 3 years	66	17
Over 3 years	10	5
	118,597	84,602

The trade payables are non-interest-bearing and are normally settled on 90-day terms.

Other Payables and Accruals

Our other payables and accruals increased from RMB204.9 million as of 31 December 2021 to RMB727.6 million as of 31 December 2022, primarily due to (i) an increase in payable for property, plant and equipment from RMB47.0 million as of 31 December 2021 to RMB104.1 million as of 31 December 2022; (ii) an increase in payroll payables from RMB41.4 million as of 31 December 2021 to RMB57.0 million as of 31 December 2022; (iii) a decrease in sales rebate from RMB33.1 million as of 31 December 2021 to RMB7.6 million as of 31 December 2022; (iv) an increase in accruals from RMB23.0 million as of 31 December 2021 to RMB51.4 million as of 31 December 2022; and (v) an increase in other current liabilities from nil as of 31 December 2021 to RMB459.5 million as of 31 December 2022, which was mainly due to the accrued liability for the minority shareholder.

	As of 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Payable for property, plant and equipment	104,050	46,956
Payroll payables	57,014	41,406
Individual income tax and other taxes	32,580	37,360
Sales rebate	7,628	33,070
Accruals	51,391	23,024
Payable for investments in joint ventures	–	20,000
Other current liability	459,517	–
Others	15,372	3,070
	<hr/>	<hr/>
Other Payables and Accruals	<u>727,552</u>	<u>204,886</u>

Indebtedness and finance lease

The following table sets forth the breakdown of our indebtedness as of the dates indicated:

	As of 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Included in current liabilities		
Lease liabilities	20,112	20,336
Other current liability	459,517	–
Convertible loan	1,197,168	–
	<hr/>	<hr/>
Included in non-current liabilities		
Lease liabilities	35,439	47,442
Long term payables	287,761	37,693
Convertible loan	–	1,200,564
	<hr/>	<hr/>
Total indebtedness	<u>1,999,997</u>	<u>1,306,035</u>

Our total indebtedness increased from RMB1,306.0 million as of 31 December 2021 to RMB2,000.0 million as of 31 December 2022, mainly due to the increase of long term payables and other current liability.

Deferred income

Our total deferred income, classified in current liabilities and non-current liabilities, increased from RMB136.3 million as of 31 December 2021 to RMB286.0 million as of 31 December 2022, mainly due to newly granted government subsidy obtained.

Property, Plant and Equipment

Property, plant and equipment increased from RMB430.1 million as of 31 December 2021 to RMB653.2 million as of 31 December 2022, which is mainly caused by increase of buildings, plant and machinery for both Beijing InnoCare and Guangzhou InnoCare.

Right-of-use Assets

The right of use assets increased from RMB136.0 million as of 31 December 2021 to RMB284.1 million as of 31 December 2022, which is mainly caused by newly increased leasehold land.

Other intangible Assets

Other intangible assets increased from RMB34.2 million as of 31 December 2021 to RMB41.3 million as of 31 December 2022 was mainly due to the addition of SAP software.

Investments in Joint Ventures

Our investments in joint ventures decreased from RMB21.4 million as of 31 December 2021 to RMB11.7 million as of 31 December 2022 because of the increase in share of losses of the joint ventures for the year increased.

Other Non-Current Assets

Other non-current assets was mainly the prepayments for long term assets, including property, plant and equipment, right-of-use assets and other intangible assets etc., as the long term assets increased, the other non-current assets decreased from RMB51.0 million as of 31 December 2021 to RMB28.0 million as of 31 December 2022.

Key Financial Ratios

The following table sets forth our selected key financial ratio:

	As of 31 December	
	2022	2021
Current ratio	4.5	19.5

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

The decrease in current ratio was primarily due to the reclassification of convertible loan from non-current liability as of 31 December 2021 to current liability as of 31 December 2022, with value of RMB1,197.2 million, the increase of other payables and accruals from RMB204.9 million as of 31 December 2021 to RMB727.6 million as of 31 December 2022, the increase of trade payables from RMB84.6 million as of 31 December 2021 to RMB118.6 million as of 31 December 2022, partially offset by increase of cash and bank balances from RMB5,928.7 million as of 31 December 2021 to RMB8,697.9 million as of 31 December 2022.

LIQUIDITY AND FINANCIAL RESOURCES

We expect our liquidity requirements to be satisfied by a combination of cash generated from operating activities, other funds raised from the capital markets from time to time and the net proceeds from the IPO and the RMB Share Issue. We will continue to evaluate potential financing opportunities based on our need for capital resources and market conditions.

On 23 March 2020, 250,324,000 Shares of US\$0.000002 each were issued at a price of HK\$8.95 per Share in connection with the Company's Listing on the Hong Kong Stock Exchange. The proceeds of HK\$3,883 representing the par value of shares, were credited to the Company's share capital. The remaining proceeds of HK\$2,240.4 million (before deduction of the expenses relating to the Company's IPO) were credited to the share premium account. The translation from U.S. dollar to Hong Kong dollar is made at the exchange rate set forth in the H.10 weekly statistical release of the Federal Reserve System of the U.S. as of 23 March 2020.

On 15 April 2020, the international underwriters of the Global Offering exercised the overallotment option in full, pursuant to which the Company is required to allot and issue the option shares, being 37,548,000 Shares, representing approximately 15% of the maximum number of shares initially available under the Global Offering, at the offer price under the Global Offering. The net proceeds from the exercise of the over-allotment option were approximately HK\$322.59 million (after deducting the commissions and other offering expenses payable by the Company in relation to the exercise of the over-allotment option).

On 10 February 2021, pursuant to two subscription agreements entered between the Company and certain investors, a total of 210,508,000 Shares of the Company were subscribed at a subscription price of HK\$14.45 per subscription share. For further details, please refer to the announcements of the Company dated 3 February 2021 and 10 February 2021, respectively.

On 21 September 2022, 264,648,217 RMB Shares of US\$0.000002 each were issued at a price of RMB11.03 per RMB Share and listed on the STAR Market. Net proceeds after deducting underwriting discounts and commission and offering expenses were RMB2,778.82 million. As required by the PRC securities laws, the net proceeds from the RMB Share Issue must be used in strict compliance with the planned uses as disclosed in the PRC prospectus as well as the Company's proceeds management policy for the RMB Share Issue approved by the board of directors.

As of 31 December 2022, our cash and bank and wealth management products balances were RMB9,011.2 million, as compared to RMB6,550.5 million as of 31 December 2021. The increase was mainly due to the net proceeds from the RMB Share Issue, and funds we received from our financing activities and operating revenue. Our primary uses of cash are to fund research and development efforts of new drug candidates, sales promotion, working capital and other general corporate purposes. Our cash and cash equivalents are held in RMB, USD, AUD and HKD.

SIGNIFICANT INVESTMENTS, MATERIAL ACQUISITIONS AND DISPOSALS

Subscription of Wealth Management Products

Between 8 October 2021 and 29 December 2021, the Company, through its subsidiaries, subscribed for certain wealth management products issued by China Merchants Bank Co., Ltd. and administered by CMB Wealth Management Company Limited, for an aggregate principal amount of RMB715 million. The relevant wealth management products are non-principal guaranteed with floating return, and with moderately low risk. As of 31 December 2022, the subscriptions generated (i) an investment income of RMB8.5 million; and (ii) a fair value gain of RMB6.6 million measured at fair value through the Company's profit/loss account. As of 31 December 2022, the aggregated outstanding principal amount of the Group's Wealth Management Products was RMB300 million. For details, please refer to the announcements of the Company dated 30 March 2022 and 19 April 2022.

Saved as disclosed above, as of 31 December 2022, we did not hold any significant investments of the Company. For the Reporting Period, we did not have any material acquisitions or disposals of subsidiaries, associates and joint ventures of the Company.

GEARING RATIO

The gearing ratio (calculated as total debt (includes other current liability, loans and borrowings and convertible loan) divided by total assets and multiplied by 100%) as of 31 December 2022 was 18.8% (31 December 2021: 17%).

The Board and the Audit Committee constantly monitor current and expected liquidity requirements to ensure that the Company maintains sufficient reserves of cash to meet its liquidity requirements in the short and long term.

BANK LOANS AND OTHER BORROWINGS

As of 31 December 2022, we had RMB1,197.2 million of the convertible loan with Guangzhou Kaide, RMB287.8 million of long-term payable with Beijing Changxin Construction Investment Co., Ltd and RMB459.5 million of other current liability with Guangzhou Hi-tech Zone Technology Holding Group Co., Ltd, land use right of RMB163.4 million was mortgaged to Beijing Changxin Construction Investment Co., Ltd. Except for the items above, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, unutilized banking facilities, bank overdrafts or other similar indebtedness, hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees.

CONTINGENT LIABILITIES

As of 31 December 2022, we did not have any material contingent liabilities.

FOREIGN EXCHANGE RISK

Our financial statements are expressed in RMB, but certain of our cash and cash equivalents, time deposits, trade and other receivables, trade and other payables are denominated in foreign currencies, and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

LIQUIDITY RISK

In the management of the liquidity risk, the Company monitors and maintains a level of cash and cash equivalents deemed adequate by its management to finance the operations and mitigate the effects of fluctuations in cash flows.

CHARGE ON GROUP ASSETS

Except for the mortgage on land use right under the paragraph of “Bank Loans and Other Borrowings”, there was no pledge of the Group’s assets as of 31 December 2022.

FINAL DIVIDEND

No dividend was declared and paid by the Group for the year ended 31 December 2022 (2021: Nil).

ANNUAL GENERAL MEETING

The forthcoming annual general meeting (“AGM”) of the Company will be held on Friday, 2 June 2023. The notice of the AGM will be published and dispatched in due course in the manner as required by the Listing Rules.

CLOSURE OF THE REGISTER OF MEMBERS

For the purpose of determining the shareholders’ eligibility to attend and vote at the AGM, the register of members of the Company will be closed from Tuesday, 30 May 2023 to Friday, 2 June 2023, both days inclusive, during which no transfer of shares of the Company will be registered. In order to be eligible to attend and vote at the AGM, all duly completed share transfer forms accompanied by the relevant share certificates, must be lodged with the Company’s Hong Kong Share Registrar, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen’s Road East, Wanchai, Hong Kong for registration not later than 4:30 p.m. on Monday, 29 May 2023.

CORPORATE GOVERNANCE AND OTHER INFORMATION

The Company was incorporated in the Cayman Islands on 3 November 2015 as an exempted company with limited liability, and the shares of the Company were listed on the Stock Exchange on 23 March 2020. On 21 September 2022, the RMB Shares of the Company were listed on the STAR Market.

AMENDMENTS TO THE MEMORANDUM AND ARTICLES OF ASSOCIATION OF THE COMPANY

At the Company's annual general meeting held on 21 June 2022, the Shareholders passed two special resolutions in relation to the amendments to (i) the Current M&A; and (ii) the RMB Share Issue M&A. The amendments are in relation to, among other things, core shareholder protection standards under Appendix 3 to the Listing Rules. The second amended and restated memorandum and articles of association of the Company became effective on 21 June 2022, and the third amended and restated memorandum and articles of association of the Company became effective on 21 September 2022. For details, please refer to the Company's circular dated 18 May 2022, and announcements dated 21 June 2022 and 20 September 2022.

CHANGES IN INFORMATION OF DIRECTORS, COMPANY SECRETARY AND CHIEF EXECUTIVES

During the Reporting Period and up to the date of this announcement, the composition of the Board of Directors, Company Secretary, and Chief Executives of the Company changed as follows:

Mr. Keith Shing Cheung Wong – tendered his resignation as (i) the Company Secretary of the Company (the “**Company Secretary**”) and has ceased to act as (ii) an authorised representative of the Company (the “**Authorised Representative**”) under Rule 3.05 of the Listing Rules; and (iii) an authorized representative of the Company under Part 16 of the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) for the acceptance of service of process and notices in Hong Kong (the “**Process Agent**”) with effect from 23 March 2022.

Ms. Angel Pui Shan Lee – appointed as the Company Secretary, the Authorised Representative and the Process Agent in replacement of Mr. Keith Shing Cheung Wong with effect from 23 March 2022.

Mr. Quanhong Yuan – resigned as a non-executive Director with effect from 31 March 2022.

Mr. Ming Jin – appointed as a non-executive Director with effect from 31 March 2022.

For details of the personal particulars of Mr. Ming Jin required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules, please refer to the announcement of the Company dated 31 March 2022.

Mr. Shaojing Tong – Mr. Shaojing Tong tendered his resignation as the chief financial officer of the Company with effect from 30 December 2022.

For details, please see the overseas regulatory announcement of the Company dated 31 December 2022.

Save as disclosed in this announcement, there are no changes in the information of Director of the Company which are required to be disclosed pursuant to Rule 13.51B(1) of the Listing Rules during the Reporting Period.

COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

The Company has applied the principles and code provisions as set out in the CG Code contained in Appendix 14 to the Listing Rules. During the Reporting Period, the Board is of the opinion that the Company has complied with all the code provisions apart from the deviation below.

Pursuant to code provision C.2.1 of the CG Code, the responsibilities between the Chairperson and the Chief Executive should be segregated and should not be performed by the same individual. The roles of the Chairperson and Chief Executive Officer of the Company are held by Dr. Jisong Cui who is a co-founder of the Company. The Board believes that this structure will not impair the balance of power and authority between our Board and the management of the Company, given that: (i) a decision to be made by the Board requires approvals by at least a majority of Directors and that the Board comprises three independent non-executive Directors out of nine Directors, and the Board believes there is sufficient check and balance in the Board; (ii) Dr. Jisong Cui and the other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that they act for the benefits and in the best interests of the Company and will make decisions for the Group accordingly; and (iii) the balance of power and authority is ensured by the operations of the Board which comprises experienced and high caliber individuals who meet regularly to discuss issues affecting the operations of the Company. Moreover, the overall strategic and other key business, financial and operational policies of the Group are made collectively after thorough discussion at both the Board and senior management levels. The Board also believes that the combined role of Chairperson and Chief Executive Officer can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Further, in view of Dr. Jisong Cui's experience, personal profile and her roles in the Company as mentioned above, Dr. Jisong Cui is the Director best suited to identify strategic opportunities and focus of the Board due to her extensive understanding of our business as the Chief Executive Officer. Finally, as Dr. Jisong Cui is the co-founder of the Company, the Board believes that vesting the roles of both Chairperson and Chief Executive Officer in the same person has the benefit of ensuring consistent leadership within the Group and enables more effective and efficient overall strategic planning for and communication within the Group. The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of Chairperson and Chief Executive Officer is necessary.

The Company will continue to regularly review this annual result and monitor the corporate governance practices to ensure the compliance with the CG Code and maintain a high standard of the best practices. We aim to implement a high standard of corporate governance, which is crucial to safeguard the interests of the Shareholders.

MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS OF LISTED ISSUERS

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the “**Model Code**”) as set out in Appendix 10 to the Listing Rules.

Specific enquiries have been made of all the Directors (including Mr. Quanhong Yuan, who resigned as a Director with effect from 31 March 2022) and they have confirmed that they have complied with the Model Code during the year ended 31 December 2022. The Company’s employees, who are likely to be in possession of unpublished inside information of the Company, are subject to the Model Code. No incident of non-compliance of the Model Code by the employees was noted by the Company during the year ended 31 December 2022.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

Save as disclosed above, neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company’s listed securities during the Reporting Period.

SCOPE OF WORK OF THE GROUP’S AUDITORS

The figures in respect of the Group’s consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended 31 December 2022 as set out in this announcement have been agreed by the Group’s auditors to the amounts set out in the Group’s audited consolidated financial statements for the year ended 31 December 2022. The work performed by the Group’s auditors in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by the Group’s auditors on this announcement.

AUDIT COMMITTEE

The Company has established the Audit Committee with written terms of reference in accordance with the Listing Rules. The Audit Committee comprises of three independent non-executive Directors, namely, Ms. Lan Hu, Dr. Zemin Jason Zhang and Dr. Kaixian Chen. Ms. Lan Hu, being the chairperson of the Audit Committee, holds the appropriate professional qualification as required under Rules 3.10(2) and 3.21 of the Listing Rules.

The Audit Committee has reviewed the audited consolidated financial statements of the Group for the year ended 31 December 2022 and has met with the independent auditors. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management members of the Company.

OTHER BOARD COMMITTEES

In addition to the Audit Committee, the Company has also established a Nomination Committee and a Compensation Committee.

MATERIAL LITIGATION

The Company was not involved in any material litigation or arbitration during the Reporting Period. The Directors are also not aware of any material litigation or claims that are pending or threatened against the Group as at the end of the Reporting Period.

USE OF NET PROCEEDS

Use of Net Proceeds from the IPO

The Shares were listed on the Main Board of the Stock Exchange on the Listing Date. The Group received net proceeds (after deduction of underwriting commissions and related costs and expenses) from the IPO and the exercise of over-allotment option of approximately HK\$2,415.67 million. Up to 31 December 2022, HKD1,260.2 million, or 52.2% out of the net proceeds have been utilized. The remaining proceeds will be used in the following three to four years. The completion time of for usage of proceeds is determined based on the Company's actual business needs and future business development.

	Use of proceeds as stated in the Prospectus <i>(in HK\$'000)</i> <i>(approximate)</i>	Net proceeds unutilized as of 31 December 2021 <i>(in HK\$'000)</i> <i>(approximate)</i>	Actual use of proceeds during 2022 <i>(in HK\$'000)</i> <i>(approximate)</i>	Net proceeds unutilized as of 31 December 2022 <i>(in HK\$'000)</i> <i>(approximate)</i>	Expected timeline for usage of proceeds
50% for ongoing and planned clinical trials, preparation for registration filings and potential commercial launches (including sales and marketing) of Orelabrutinib concurrently in both China and the U.S.	1,207,835	853,114	441,116	411,998	The amount is expected to be fully utilized before the second half of 2026
40% for our other clinical stage product candidates*	966,268	812,054	115,853	696,201	The amount is expected to be fully utilized before the second half of 2026
10% for working capital and general corporate purposes	241,567	63,666	16,350	47,316	The amount is expected to be fully utilized before the second half of 2026
Total	2,415,670	1,728,834	573,319	1,155,515	

* Comparing to the corresponding disclosures in the Prospectus, or in previous annual reports, in this report the Company has adjusted the manner in which the proceeds from its IPO will be applied to. Such adjustments are to (i) better reflect the recent advancement of progress in the Company's product pipelines, and (ii) demonstrate the Company's recent development focus in its product pipelines.

Use of Net Proceeds from Subscription Agreements in February 2021

On 2 February 2021, the Company and certain investors had entered into two subscription agreements pursuant to which the Company has conditionally agreed to allot and issue and the investors, namely Gaoling Fund L.P., YHG Investment L.P. and Vivo Opportunity Fund, L.P., have conditionally, on a several but not joint basis, agreed to subscribe for an aggregate of 210,508,000 Shares of the Company, representing approximately 16.33% of the then total issued shares of the Company as at the date of the subscription agreements and approximately 14.04% of the total issued shares of the Company as enlarged by the allotment and issue of the subscription shares, at the subscription price of HK\$14.45 per subscription share. The aggregate nominal value of the subscription shares under the subscription was US\$421.02. The net price of each subscription share based on the net proceeds of approximately HK\$3,041.44 million and 210,508,000 subscription shares were estimated to be approximately HK\$14.45. The closing price as quoted on the Stock Exchange on 2 February 2021 was HK\$15.72 per Share. The gross proceeds and net proceeds from the issued subscription shares were approximately HK\$3,041.84 million and HK\$3,041.44 million, respectively. The above-mentioned subscription was completed on 10 February 2021. Such use of proceeds will be in line with the planned use according to the intentions previously disclosed by the Company and it is expected there will be no significant change or delay.

The table below sets out the planned applications of the proceeds and actual usage up to 31 December 2022:

	Proceeds from the subscription <i>(in HK\$'000)</i> <i>(approximate)</i>	Actual use of proceeds up to 31 December 2022 <i>(in HK\$'000)</i> <i>(approximate)</i>	Net proceeds unutilized as of 31 December 2022 <i>(in HK\$'000)</i> <i>(approximate)</i>	Expected timeline for usage of proceeds
Business objectives as stated in the announcement of the Company dated 3 February 2021	3,041,440	1,704,498	1,336,942	Expected to be fully utilized in three years since 23 March 2021, and subject to, among other things, change of market conditions

Use of Net Proceeds from RMB Share Issue

On 21 September 2022, the RMB Shares were listed on the STAR Market. The gross proceeds amounted to approximately RMB2,919.07 million. After deducting issuance expenses of RMB140.25 million in accordance with the related requirements, the net proceeds amounted to approximately RMB2,778.82 million. The net proceeds raised from the RMB Share Issue have been used and will be used in accordance with the intended uses disclosed in the Company's RMB Share prospectus dated 16 September 2022, which has been attached to the overseas regulatory announcement of the Company dated 16 September 2022. In January 2023, a fund displacement report was issued that RMB545.7 million could be displaced by the raised fund.

As at 31 December 2022, none of the net proceeds of the RMB Share Issue had been utilised as follows:

	Proceeds from the subscription <i>(in RMB'000)</i> <i>(approximate)</i>	Actual use of proceeds up to 31 December 2022 <i>(in RMB'000)</i> <i>(approximate)</i>	Net proceeds unutilized as of 31 December 2022 <i>(in RMB'000)</i> <i>(approximate)</i>	Expected timeline for usage of proceeds
New drug research and development ("R&D") projects	1,494,220.6	-	1,494,220.6	Expected to be fully utilized by 2027, and subject to, among other things, change of market conditions
Upgrade of drug R&D platform	116,146.6	-	116,146.6	Expected to be fully utilized by 2027, and subject to, among other things, change of market conditions
Construction of marketing network	273,851.4	-	273,851.4	Expected to be fully utilized by 2027, and subject to, among other things, change of market conditions
Construction of IT system	60,952.3	-	60,952.3	Expected to be fully utilized by 2027, and subject to, among other things, change of market conditions
Replenishment of cash flow	833,644.7	-	833,644.7	Expected to be fully utilized by 2027, and subject to, among other things, change of market conditions
Total	<u>2,778,815.6</u>	<u>-</u>	<u>2,778,815.6</u>	

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2022

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2022

	<i>Notes</i>	2022 RMB'000	2021 RMB'000
REVENUE	4	625,404	1,043,033
Cost of sales		<u>(143,397)</u>	<u>(65,667)</u>
Gross profit		482,007	977,366
Other income and gains	4	198,199	217,938
Selling and distribution expenses		(438,611)	(298,463)
Research and development expenses		(639,139)	(721,584)
Administrative expenses		(181,556)	(139,815)
Other expenses		(291,167)	(1,271)
Fair value changes of convertible loan		3,396	(51,014)
Impairment losses on financial assets		(100)	(32)
Share of losses of joint ventures		(9,711)	(604)
Finance costs		<u>(17,045)</u>	<u>(2,642)</u>
LOSS BEFORE TAX		(893,727)	(20,121)
Income tax expense	5	<u>–</u>	<u>(46,558)</u>
LOSS FOR THE YEAR		<u>(893,727)</u>	<u>(66,679)</u>
Attributable to:			
Owners of the parent		(886,593)	(64,545)
Non-controlling interests		<u>(7,134)</u>	<u>(2,134)</u>
		<u>(893,727)</u>	<u>(66,679)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
– Basic and diluted	7	<u>(RMB0.60)</u>	<u>(RMB0.05)</u>

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2022

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
LOSS FOR THE YEAR	<u>(893,727)</u>	<u>(66,679)</u>
OTHER COMPREHENSIVE LOSS		
Other comprehensive loss that may not be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>429,445</u>	<u>(89,453)</u>
OTHER COMPREHENSIVE LOSS FOR THE YEAR, NET OF TAX	<u>429,445</u>	<u>(89,453)</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	<u>(464,282)</u>	<u>(156,132)</u>
Attributable to:		
Owners of the parent	(457,148)	(153,998)
Non-controlling interests	<u>(7,134)</u>	<u>(2,134)</u>
	<u>(464,282)</u>	<u>(156,132)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
31 December 2022

	<i>Notes</i>	2022 RMB'000	2021 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		653,163	430,081
Right-of-use assets		284,103	135,999
Goodwill		3,125	3,125
Other intangible assets		41,305	34,166
Investments in joint ventures		11,712	21,423
Financial assets at fair value through profit or loss		–	304,675
Other non-current assets		28,042	50,951
		<hr/>	<hr/>
Total non-current assets		1,021,450	980,420
CURRENT ASSETS			
Inventories		65,322	9,918
Trade receivables	8	127,825	45,273
Prepayments, other receivables and other assets		95,344	116,145
Financial assets at fair value through profit or loss		313,290	317,059
Cash and bank balances		8,697,927	5,928,716
		<hr/>	<hr/>
Total current assets		9,299,708	6,417,111
CURRENT LIABILITIES			
Trade payables	9	118,597	84,602
Contract liabilities		4,242	6,831
Other payables and accruals		727,552	204,886
Deferred income		7,757	12,647
Lease liabilities		20,112	20,336
Convertible loan		1,197,168	–
		<hr/>	<hr/>
Total current liabilities		2,075,428	329,302
NET CURRENT ASSETS		<hr/> 7,224,280 <hr/>	<hr/> 6,087,809 <hr/>
TOTAL ASSETS LESS CURRENT LIABILITIES		<hr/> 8,245,730 <hr/>	<hr/> 7,068,229 <hr/>
NON-CURRENT LIABILITIES			
Convertible loan		–	1,200,564
Lease liabilities		35,439	47,442
Long term payables		287,761	37,693
Deferred income		278,203	123,611
		<hr/>	<hr/>
Total non-current liabilities		601,403	1,409,310
Net assets		<hr/> 7,644,327 <hr/>	<hr/> 5,658,919 <hr/>
EQUITY			
Equity attributable to owners of the parent			
Share capital		23	19
Reserves		7,597,078	5,604,540
		<hr/>	<hr/>
Non-controlling interests		7,597,101	5,604,559
		47,226	54,360
		<hr/>	<hr/>
Total equity		<hr/> 7,644,327 <hr/>	<hr/> 5,658,919 <hr/>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. CORPORATE INFORMATION

The Company is a limited liability company incorporated in the Cayman Islands on 3 November 2015. The registered office of the Company is located at the offices of Ogier Global (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9009, Cayman Islands.

The Company is an investment holding company. The Company's subsidiaries are principally engaged in the research, development, manufacture and commercialization of biological products. The Company's ordinary shares were listed on the Main Board of the Stock Exchange of Hong Kong Limited (the "Hong Kong Stock Exchange") and STAR Market of the Shanghai Stock Exchange on 23 March 2020 and on 21 September 2022, respectively.

Information about the subsidiaries

Particulars of the Company's subsidiaries are as follows:

Name	Place of incorporation/ registration and business	Nominal value of issued ordinary/ registered share capital	Percentage of equity interest attributable to the Company		Principal activities
			Direct	Indirect	
Ocean Prominent Limited	British Virgin Islands	US\$1	100%	–	Investment holding
Sunny Investments Limited	Hong Kong	HK\$1	–	100%	Investment holding
InnoCare Pharma Inc.	United States of America ("USA")	US\$10,000,000	–	100%	Research and development
InnoCare Pharma Australia Pty Ltd.	Australia	AU\$10	–	100%	Research and development
Beijing InnoCare Pharma Tech Co., Ltd. ("Beijing InnoCare") ^(a)	PRC/Mainland China	US\$80,000,000	–	100%	Research and development
Nanjing Tianyin Jian Hua Pharma Tech Co., Ltd. ("Nanjing InnoCare")	PRC/Mainland China	RMB10,000,000	–	100%	Research and development
Beijing Tiancheng Pharma Tech Co., Ltd.	PRC/Mainland China	RMB49,225,100	–	91.08%	Research and development
Shanghai Tianjin Pharma Tech Co., Ltd.	PRC/Mainland China	RMB4,000,000	–	100%	Research and development
Guangzhou InnoCare Pharma Tech Co., Ltd. ("Guangzhou InnoCare")	PRC/Mainland China	RMB1,000,000,000	–	93%	Development and manufacturing
Guangzhou InnoCare Biological Tech Co., Ltd. ^(a)	PRC/Mainland China	US\$30,000,000	–	100%	Research and development

(a) Registered as wholly-foreign-owned enterprises under PRC law.

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with Hong Kong Financial Reporting Standards (“HKFRSs”) (which include all Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards (“HKASs”) and Interpretations) issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”), accounting principles generally accepted in Hong Kong and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for financial assets at fair value through profit or loss and convertible loan which have been measured at fair value. These financial statements are presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand except when otherwise indicated.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the “Group”) for the year ended 31 December 2022. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following revised HKFRSs for the first time for the current year's financial statements.

Amendments to HKFRS 3	<i>Reference to the Conceptual Framework</i>
Amendments to HKAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i>
Amendments to HKAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract</i>
<i>Annual Improvements to HKFRSs 2018-2020</i>	Amendments to HKFRS 1, HKFRS 9, Illustrative Examples accompanying HKFRS 16, and HKAS 41

The nature and the impact of the revised HKFRSs that are applicable to the Group are described below:

- (a) Amendments to HKFRS 3 replace a reference to the previous Framework for the Preparation and Presentation of Financial Statements with a reference to the Conceptual Framework for Financial Reporting (the “Conceptual Framework”) issued in June 2018 without significantly changing its requirements. The amendments also add to HKFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of HKAS 37 or HK(IFRIC)-Int 21 if they were incurred separately rather than assumed in a business combination, an entity applying HKFRS 3 should refer to HKAS 37 or HK(IFRIC)-Int 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no contingent assets, liabilities and contingent liabilities within the scope of the amendments arising in the business combination that occurred during the year, the amendments did not have any impact on the financial position and performance of the Group.
- (b) Amendments to HKAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items as determined by HKAS 2 Inventories, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced prior to the property, plant and equipment being available for use, the amendments did not have any impact on the financial position or performance of the Group.
- (c) Amendments to HKAS 37 clarify that for the purpose of assessing whether a contract is onerous under HKAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.
- (d) *Annual Improvements to HKFRSs 2018-2020* sets out amendments to HKFRS 1, HKFRS 9, Illustrative Examples accompanying HKFRS 16, and HKAS 41. Details of the amendments that are applicable to the Group are as follows:
- *HKFRS 9 Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively from 1 January 2022. As there was no modification or exchange of the Group's financial liabilities during the year, the amendment did not have any impact on the financial position or performance of the Group.

2.3 ISSUED BUT NOT YET EFFECTIVE HONG KONG FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised HKFRSs, that have been issued but are not yet effective, in these financial statements.

Amendments to HKFRS 10 and HKAS 28 (2011)	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to HKFRS 16	<i>Lease Liability in a Sale and Leaseback</i> ²
HKFRS 17	<i>Insurance Contracts</i> ¹
Amendments to HKFRS 17	<i>Insurance Contracts</i> ^{1,5}
Amendment to HKFRS 17	<i>Initial Application of HKFRS 17 and HKFRS 9 – Comparative Information</i> ⁶
Amendments to HKAS 1	<i>Classification of Liabilities as Current or Non-current (the “2020 Amendments”)</i> ^{2,4}
Amendments to HKAS 1	<i>Non-current Liabilities with Covenants (the “2022 Amendments”)</i> ²
Amendments to HKAS 1 and HKFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i> ¹
Amendments to HKAS 8	<i>Definition of Accounting Estimates</i> ¹
Amendments to HKAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i> ¹

¹ Effective for annual periods beginning on or after 1 January 2023

² Effective for annual periods beginning on or after 1 January 2024

³ No mandatory effective date yet determined but available for adoption

⁴ As a consequence of the 2022 Amendments, the effective date of the 2020 Amendments was deferred to annual periods beginning on or after 1 January 2024. In addition, as a consequence of the 2020 Amendments and 2022 Amendments, Hong Kong Interpretation 5 *Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause* was revised to align the corresponding wording with no change in conclusion

⁵ As a consequence of the amendments to HKFRS 17 issued in October 2020, HKFRS 4 was amended to extend the temporary exemption that permits insurers to apply HKAS 39 rather than HKFRS 9 for annual periods beginning before 1 January 2023

⁶ An entity that chooses to apply the transition option relating to the classification overlay set out in this amendment shall apply it on initial application of HKFRS 17

Further information about those HKFRSs that are expected to be applicable to the Group is described below.

Amendments to HKFRS 10 and HKAS 28 (2011) address an inconsistency between the requirements in HKFRS 10 and in HKAS 28 (2011) in dealing with the sale or contribution of assets between an investor and its associate or joint venture. The amendments require a full recognition of a gain or loss resulting from a downstream transaction when the sale or contribution of assets between an investor and its associate or joint venture constitutes a business. For a transaction involving assets that do not constitute a business, a gain or loss resulting from the transaction is recognised in the investor’s profit or loss only to the extent of the unrelated investor’s interest in that associate or joint venture. The amendments are to be applied prospectively. The previous mandatory effective date of amendments to HKFRS 10 and HKAS 28 (2011) was removed by the HKICPA in January 2016 and a new mandatory effective date will be determined after the completion of a broader review of accounting for associates and joint ventures. However, the amendments are available for adoption now.

Amendments to HKFRS 16 specify the requirements that a seller-lessee uses in measuring the lease liability arising in a sale and leaseback transaction to ensure the seller-lessee does not recognise any amount of the gain or loss that relates to the right of use it retains. The amendments are effective for annual periods beginning on or after 1 January 2024 and shall be applied retrospectively to sale and leaseback transactions entered into after the date of initial application of HKFRS 16 (i.e., 1 January 2019). Earlier application is permitted. The amendments are not expected to have any significant impact on the Group’s financial statements.

Amendments to HKAS 1 *Classification of Liabilities as Current or Non-current* clarify the requirements for classifying liabilities as current or non-current, in particular the determination over whether an entity has a right to defer settlement of the liabilities for at least 12 months after the reporting period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement of the liability. The amendments also clarify the situations that are considered a settlement of a liability. In 2022, the HKICPA issued the 2022 Amendments to further clarify that, among covenants of a liability arising from a loan arrangement, only those with which an entity must comply on or before the reporting date affect the classification of that liability as current or non-current. In addition, the 2022 Amendments require additional disclosures by an entity that classifies liabilities arising from loan arrangements as non-current when it has a right to defer settlement of those liabilities that are subject to the entity complying with future covenants within 12 months after the reporting period. The amendments are effective for annual periods beginning on or after 1 January 2024 and shall be applied retrospectively. Earlier application is permitted. An entity that applies the 2020 Amendments early is required to apply simultaneously the 2022 Amendments, and vice versa. The Group is currently assessing the impact of the amendments and whether existing loan agreements may require revision. Based on a preliminary assessment, the amendments are not expected to have any significant impact on the Group's financial statements

Amendments to HKAS 1 *Disclosure of Accounting Policies* require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to HKFRS Practice Statement 2 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. Amendments to HKAS 1 are effective for annual periods beginning on or after 1 January 2023 and earlier application is permitted. Since the guidance provided in the amendments to HKFRS Practice Statement 2 is non-mandatory, an effective date for these amendments is not necessary. The Group is currently revisiting the accounting policy disclosures to ensure consistency with the amendments.

Amendments to HKAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and apply to changes in accounting policies and changes in accounting estimates that occur on or after the start of that period. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to HKAS 12 narrow the scope of the initial recognition exception in HKAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions. The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and shall be applied to transactions related to leases and decommissioning obligations at the beginning of the earliest comparative period presented, with any cumulative effect recognised as an adjustment to the opening balance of retained profits or other component of equity as appropriate at that date. In addition, the amendments shall be applied prospectively to transactions other than leases and decommissioning obligations. Earlier application is permitted.

The Group has applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. Upon initial application of these amendments, the Group will recognise deferred tax for all temporary differences related to leases at the beginning of the earliest comparative period presented. During the year, the Group has performed a detailed assessment on the impact of amendments to HKAS 12. The Group has estimated that it will recognise a deferred tax asset of RMB7,852,000 for deductible temporary differences associated with lease liabilities and a deferred tax liability of RMB7,877,000 for taxable temporary differences associated with right-of-use assets, and recognise the cumulative effect of initially applying the amendments as an adjustment to retained profits at 1 January 2022.

3. OPERATING SEGMENT INFORMATION

Since the Group's revenue and operating losses were mainly from the activities related to research and development and manufacturing in Mainland China, and most of the Group's identifiable operating assets and liabilities are located in Mainland China, the Group only has one reportable operating segment.

Geographical information

(a) Revenue from external customers

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
– Mainland China	568,035	216,066
– Overseas	57,369	826,967
	<u>625,404</u>	<u>1,043,033</u>

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
– Mainland China	1,020,695	674,729
– Overseas	755	1,016
	<u>1,021,450</u>	<u>675,745</u>

The non-current asset information above is based on the locations of the assets and excludes deferred tax assets and financial instruments.

Information about major customers

Revenue from each of the major customers (aggregated if under common control) which accounted for 10% or more of the Group's revenue during the year is set out below:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Customer A	*	826,967
Customer B	224,090	*
Customer C	101,386	*
Customer D	81,916	*
	<u>407,392</u>	<u>826,967</u>

* The corresponding revenue of the customer is not disclosed as the revenue individually did not account for 10% or more of the Group's revenue for the years ended 31 December 2021 and 2022.

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue from contracts with customers	<u>625,404</u>	<u>1,043,033</u>

(a) **Disaggregated revenue information**

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue from contracts with customers		
– License out	–	775,963
– Sales of goods	566,755	214,666
– Research and development services	57,369	51,003
– Other services	1,280	1,401
	<u>625,404</u>	<u>1,043,033</u>
Geographical markets		
– Mainland China	568,035	216,066
– Overseas	57,369	826,967
	<u>625,404</u>	<u>1,043,033</u>
Timing of revenue recognition		
– Goods and service transferred at a point in time	568,035	992,030
– Services transferred over time (<i>note</i>)	57,369	51,003
	<u>625,404</u>	<u>1,043,033</u>

Note: In February 2023, Biogen Inc. (“Biogen”) notified the Company of its decision to terminate its license and collaboration agreement with the Company, an oral small molecule Bruton’s tyrosine kinase (“BTK”) inhibitor for the potential treatment of Multiple Sclerosis (“MS”) along with the research and development services. Following the termination, the Company will regain all global rights granted to Biogen, including related intellectual property, decision-making regarding research and development, manufacturing, and commercialization, and commercial proceeds generated from orelabrutinib. The Company and Biogen will collaborate to complete the transition within 90 days.

The following table shows the amounts of revenue recognised in the current reporting period that were included in the contract liabilities at the beginning of the reporting period.

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Research and development services	<u>7,797</u>	<u>–</u>

(b) **Performance obligations**

Information about the Group’s performance obligations is summarised below:

License out and research and development services

The performance obligation is satisfied at a point in time or over time as output generated from upon completion of transfer of know-how or the research and development activities is supplied to the customer, and payment is generally due within 60 days from the date of billing.

Sales of goods

The performance obligation is satisfied upon delivery of the goods and payment is generally due within 30 to 90 days from the date of billing.

Other services

The performance obligation is satisfied upon delivery of the testing service reports and payment is generally due within 90 days from delivery.

The transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December are as follows:

	2022 RMB'000	2021 RMB'000
Amounts expected to be recognised as revenue		
Within one year	17,783	7,797
After one year	–	17,783
	<u>17,783</u>	<u>25,580</u>

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognised as revenue within one year. The amounts disclosed above do not include variable consideration which is constrained.

	2022 RMB'000	2021 RMB'000
<u>Other income</u>		
Government grants (<i>note</i>)	46,159	16,257
Bank interest income	136,914	135,135
Investment income of investments from wealth management products	8,486	70
Others	83	2,608
	<u>191,642</u>	<u>154,070</u>
<u>Gains</u>		
Fair value changes of financial assets at fair value through profit or loss	6,557	6,733
Foreign exchange gains, net	–	57,135
	<u>198,199</u>	<u>217,938</u>

Note: Government grants have been received from the PRC local government authorities to support the subsidiaries' research and development activities and compensate capital expenditures.

5. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

British Virgin Islands

Under the current laws of the British Virgin Islands ("BVI"), Ocean Prominent Limited is not subject to tax on income or capital gains. In addition, upon payments of dividends by Ocean Prominent Limited to its shareholder, no BVI withholding tax is imposed.

Hong Kong

The subsidiary incorporated in Hong Kong is subject to income tax at the rate of 16.5% (2021: 16.5%) on the estimated assessable profits arising in Hong Kong during the year which is a qualifying entity under the two-tiered profits tax rates regime. The first HK\$2,000,000 (2021: HK\$2,000,000) of assessable profits of this subsidiary are taxed at 8.25% (2021: 8.25%) and the remaining assessable profits are taxed at 16.5% (2021: 16.5%).

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income. Preferential tax treatment of 15% is available to entities recognised as High and New Technology Enterprises. Beijing InnoCare, Nanjing InnoCare and Guangzhou InnoCare were recognised as High and New Technology Enterprises and are entitled to a preferential tax rate of 15% in 2022 (2021: Beijing InnoCare, 15%; Nanjing InnoCare, up for renewal; Guangzhou InnoCare, 25%)

Australia

The subsidiary incorporated in Australia is subject to income tax at the rate of 25% (2021: 26%) on the estimated assessable profits during the year which is a qualifying entity with less than Australian Dollar 50,000,000 of turnover and 30% (2021: 30%) on the estimated assessable profits during the year which is a qualifying entity with more than Australian Dollar 50,000,000 of turnover.

United States of America

The subsidiary incorporated in United States is subject to statutory United States federal corporate income tax at a rate of 21% (2021: 21%). It is also subject to the state income tax in relevant states to fulfil compliance requirement.

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Current income tax expense	–	52,593
Deferred income tax expense	–	(6,035)
	<u>–</u>	<u>46,558</u>

A reconciliation of the tax expense applicable to loss before tax using the statutory rate for the jurisdictions in which the Company and its subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Loss before tax	<u>(893,727)</u>	<u>(20,121)</u>
Tax at the statutory tax rate of 25%	(223,432)	(5,030)
Effect of tax rate differences in other jurisdictions	97,152	22,370
Preferential tax rates applicable to certain subsidiaries	65,183	(23,565)
Additional deductible allowance for qualified research and development costs	(62,491)	(56,802)
Income not subject to tax	–	(82,003)
Tax losses not recognised	103,983	134,184
Expenses not deductible for tax	18,148	4,720
Losses attributable to joint ventures	1,457	91
Withholding tax from license and collaboration revenue	–	52,593
Tax charge at the Group's effective rate	<u>–</u>	<u>46,558</u>

The Group has tax losses arising in Mainland China of RMB1,511,700,000 that will expire in one to ten years for offsetting against future taxable profits.

Deferred tax assets have not been recognised in respect of these losses as they have arisen in subsidiaries that have been loss-making for some time and it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

6. DIVIDEND

No dividends have been declared and paid by the Company for the year ended 31 December 2022 (2021: Nil).

7. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic and diluted loss per share amounts attributable to ordinary equity holders of the parent is based on the following data:

	Year ended 31 December	
	2022	2021
	RMB'000	RMB'000
<u>Loss</u>		
Loss for the year attributable to ordinary equity holders of the parent, used in the basic and diluted loss per share calculation	<u>(886,593)</u>	<u>(64,545)</u>
	2022	2021
	Number of shares	Number of shares
	'000	'000
<u>Shares</u>		
Weighted average number of ordinary shares in issue during the year used in the basic and diluted loss per share calculation	<u>1,479,565</u>	<u>1,366,261</u>

The computation of basic and diluted loss per share for the years ended 31 December 2022 and 2021 excluded the unvested restricted stock units of the Company.

As the Group incurred losses, no adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2022 and 2021 in respect of a dilution as the impact of the conversion of the exercise of restricted stock units, had an anti-dilutive effect on the basic loss per share amounts presented. Accordingly, the dilutive loss per share amounts for the years ended 31 December 2022 and 2021 are the same as the basic loss per share amounts.

8. TRADE RECEIVABLES

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Trade receivables	127,957	45,304
Impairment	<u>(132)</u>	<u>(31)</u>
Trade receivables	<u>127,825</u>	<u>45,273</u>

The Group's trading terms with its customers are mainly on credit, except for new customers, where payment in advance is normally required. The credit period is generally one month, extending up to three months for major customers. Each customer has a maximum credit limit. The Group seeks to maintain strict control over its outstanding receivables to minimise credit risk. Overdue balances are reviewed regularly by senior management. In view of the aforementioned and the fact that the Group's trade receivables relate to several diversified customers, there is no significant concentration of credit risk. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

An ageing analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 3 months	127,822	45,273
3 months to 6 months	<u>3</u>	<u>–</u>
	<u>127,825</u>	<u>45,273</u>

The movements in the loss allowance for impairment of trade receivables are as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
At beginning of year	31	–
Impairment losses	100	32
Foreign exchange differences	1	–
Amount written off as uncollectible	<u>–</u>	<u>(1)</u>
At end of year	<u>132</u>	<u>31</u>

An impairment analysis is performed at each reporting date using a provision matrix to measure expected credit losses. The provision is based on exposure at default, probability of default and loss given default. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions.

Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

As at 31 December 2022

	Gross carrying amount <i>RMB'000</i>	Expected loss rate	Expected credit loss <i>RMB'000</i>
Trade receivables aged Less than 1 year	<u>127,957</u>	<u>0.10%</u>	<u>132</u>

As at 31 December 2021

	Gross carrying amount <i>RMB'000</i>	Expected loss rate	Expected credit loss <i>RMB'000</i>
Trade receivables aged Less than 1 year	<u>45,304</u>	<u>0.07%</u>	<u>32</u>

9. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of the reporting period, based on the invoice date, is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 1 year	111,186	84,459
1 year to 2 years	7,335	121
2 years to 3 years	66	17
Over 3 years	<u>10</u>	<u>5</u>
	<u>118,597</u>	<u>84,602</u>

The trade payables are non-interest-bearing and are normally settled on 90-day terms.

10. EVENTS AFTER THE REPORTING PERIOD

In February 2023, Biogen notified the Company of its decision to terminate its license and collaboration agreement with InnoCare for orelabrutinib, an oral small molecule BTK inhibitor for the potential treatment of MS along with the research and development services. Following the termination, the Company will regain all global rights granted to Biogen, including related intellectual property, decision-making regarding research and development, manufacturing, and commercialization, and commercial proceeds generated from orelabrutinib. The Company and Biogen will collaborate to complete the transition within 90 days.

PUBLICATION OF THE ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This annual results announcement is published on the website of the Stock Exchange at www.hkexnews.hk and the website of the Company at www.innocarepharma.com. The annual report of the Group for the year ended 31 December 2022 will be published on the aforesaid websites of the Stock Exchange and the Company, and will be dispatched to the Company's shareholders on or before 30 April 2023.

GLOSSARY AND DEFINITIONS

In this announcement, unless the context otherwise requires, the following terms have the following meanings. These terms and their definitions may not correspond to any industry standard definition, and may not be directly comparable to similarly titled terms adopted by other companies operating in the same industries as the Company.

“AD”	atopic dermatitis
“AGM”	annual general meeting of the Company
“ALL”	acute lymphoblastic leukemia
“AML”	acute myeloid leukemia
“AQP4 IgG”	aquaporin 4 antibody
“ASH”	American Society of Hematology
“AUD”	Australian dollars, the lawful currency of Australia
“Audit Committee”	the audit committee of the Board
“B-cell”	a type of white blood cell that differs from other lymphocytes like T-cells by the presence of the BCR on the B-cell's outer surface. Also known as B-lymphocytes
“Biogen”	Biogen Inc. (Nasdaq: BIIB)
“Board”	the board of directors of our Company
“BTD”	breakthrough therapy designation
“BTK”	Bruton's tyrosine kinase, a human enzyme encoded by the BTK Gene
“CD20”	B-lymphocyte antigen CD20, a B-cell specific cell surface molecule that is encoded by the MS4A1 gene
“CDC”	complement-dependent cytotoxicity
“CDE”	Center for Drug Evaluation, an institution under the NMPA

“CEO” or “Chief Executive Officer”	the chief executive officer of the Company
“CG Code”	the Corporate Governance Code set out in Appendix 14 of the Listing Rules
“Chairperson”	Chairperson of the Board
“China” or “PRC”	the People’s Republic of China, which for the purpose of this announcement and for geographical reference only, excludes Hong Kong, Macau and Taiwan
“cholangiocarcinoma”	bile duct cancer, a type of cancer that forms in the bile ducts
“CLL”	chronic lymphocytic leukemia
“CNSL”	central nervous system lymphoma
“Company”, “our Company”, “the Company” or “InnoCare”	InnoCare Pharma Limited (Stock code: 9969), an exempted company with limited liability incorporated under the laws of the Cayman Islands on 3 November 2015, the shares of which are listed on the Main Board of the Hong Kong Stock Exchange on 23 March 2020
“Compensation Committee”	the compensation committee of the Board
“Director(s)”	the director(s) of the Company
“DLBCL”	diffuse large B-cell lymphoma, a common type of non-Hodgkin lymphoma that starts in lymphocytes
“DLT”	dose-limiting toxicity, side effects of a drug or other treatment that are serious enough to prevent an increase in dose or level of that treatment
“EULAR”	the European Alliance of Associations for Rheumatology
“FGFR”	fibroblast growth factor receptor, membrane-spanning proteins that are a subgroup of the family of tyrosine kinase receptors
“FL”	follicular lymphoma
“Global Offering”	the Hong Kong public offering and the international offering of the Shares
“GMP”	good manufacturing practice
“Group”, “our Group”, “the Group”, “we”, “us” or “our”	the Company and its subsidiaries from time to time

“Guangzhou Kaide”	Guangzhou Kaide Technology Development Co., Ltd., which was renamed as Guangzhou Development Zone Financial Holding Group Co., Ltd since September 2019
“HK\$” or “HKD”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“Hong Kong Stock Exchange” or “Stock Exchange” or “HKEx”	The Stock Exchange of Hong Kong Limited
“IBD”	inflammatory bowel disease
“ICP-105”	one of the Company’s clinical stage drug candidates
“ICP-192”	one of the Company’s clinical stage drug candidates
“ICP-022” or “Orelabrutinib”	one of the Company’s clinical stage drug candidates
“iDMC”	Independent Data Monitoring Committee
“IL-2”	interleukin-2
“IL-5”	interleukin-5
“IL-12”	interleukin-12
“IL-23”	interleukin-23
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or clinical trial notification in Australia
“IPO”	the initial public offering of the Company on the Hong Kong Stock Exchange
“IRC”	Independent Review Board/Committee
“ITK”	inducible T cell Kinase
“ITP”	Immune Thrombocytopenia
“iwNHL”	International Working Group Criteria for Non-Hodgkin Lymphoma
“JAK”	janus tyrosine kinase
“Listing”	the listing of the Shares on the Main Board of the Hong Kong Stock Exchange

“Listing Date”	23 March 2020, being the date on which the Shares of the Company were listed on the Hong Kong Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited
“MCD”	a subtype of diffuse large B-cell lymphoma (DLBCLs), based on co-occurrence of MYD88L265P and CD79B mutations (MCD subtype)
“MCL”	mantle cell lymphoma, a type of B-cell non-Hodgkin lymphoma
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 of the Listing Rules
“MS”	multiple sclerosis
“MZL”	marginal zone lymphoma
“NDA”	new drug application
“NMOSD”	neuromyelitis optic a spectrum disorder, also known as demyelinating autoimmune disease, is a chronic disorder of the brain and spinal cord dominated by inflammation of the optic nerve (optic neuritis) and inflammation of the spinal cord (myelitis)
“NMPA”	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理局)
“Nomination Committee”	the nomination committee of the Board
“NRDL”	National reimbursement drug list
“NTRK”	neurotrophic tyrosine receptor kinase
“pan-FGFR inhibitor”	pan-inhibitor of fibroblast growth factor receptor (FGFR) family
“pan-TRK inhibitor”	pan-inhibitor of tropomyosin-related kinase family
“pharmacodynamics” or “PD”	the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
“pharmacokinetics” or “PK”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“Prospectus”	the prospectus of the Company, dated 11 March 2020, in relation of its Global Offering

“R&D”	research and development
“R/R” or “r/r”	relapsed and refractory
“R-CHOP”	a combination of five drugs as first-line treatment for aggressive non-Hodgkin lymphoma
“RICE”	a combination of four drugs as a treatment for non-Hodgkin lymphoma or Hodgkin lymphoma that has come back after treatment.
“RMB”	Renminbi, the lawful currency of the PRC
“RMB Share Issue”	the Company’s initial issue of no more than 264,648,217 RMB Shares which have been listed on the STAR Market since 21 September 2022
“RMB Shares”	the ordinary Shares to be subscribed for in RMB by target subscribers in the PRC, to be listed on the STAR Market and traded in RMB
“SC”	subcutaneous
“Share(s)”	ordinary shares in the share capital of our Company with a nominal value of US\$0.000002 each
“Shareholder(s)”	holder(s) of Share(s)
“SHP2”	non-receptor protein tyrosine phosphatase involved in mediating RAS signaling pathway and immune checkpoint pathway as well for regulation of cellular proliferation and survival
“SLE”	systemic lupus erythematosus
“SLL”	small lymphocytic lymphoma
“SRI”	the SLE Responder Index
“STAR Market”	the Science and Technology Innovation Board of the Shanghai Stock Exchange
“T-cell”	a type of lymphocyte produced or processed by the thymus gland and actively participating in the immune response. T-cells can be distinguished from other lymphocytes, such as B-cells and NK cells, by the presence of a T-cell receptor on the cell surface
“TDCC”	T-cell-dependent cellular cytotoxicity
“TRK”	a family of tyrosine kinases that regulates synaptic strength and plasticity in the mammalian nervous system

“TYK2”	tyrosine kinase 2
“UC” or “urothelial cancer”	urothelial cell carcinoma, a type of cancer that typically occurs in the urinary system and begins in urothelial cells
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. FDA” or “FDA”	U.S. Food and Drug Administration
“US\$” or “USD”	United States dollars, the lawful currency of the United States
“Vivo”	Vivo Opportunity Fund, L.P, a company of Vivo Capital VIII, LLC
“WM”	Waldenstrom’s macroglobulinemia

APPRECIATION

The Board would like to express its sincere gratitude to the shareholders, management team, employees, business partners and customers of the Group for their support and contribution to the Group.

By order of the Board
InnoCare Pharma Limited
Dr. Jisong Cui
Chairperson and Executive Director

Hong Kong, 27 March 2023

As at the date of this announcement, the Board comprises Dr. Jisong Cui as Chairperson and executive Director, Dr. Renbin Zhao as executive Director, Dr. Yigong Shi, Mr. Ronggang Xie and Mr. Ming Jin as non-executive Directors, and Dr. Zemin Jason Zhang, Ms. Lan Hu and Dr. Kaixian Chen as independent non-executive Directors.