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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 2021**

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 2021 (the “**Reporting Period**”), together with the comparative figures for the year ended 31 December 2020. 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.

### **BUSINESS HIGHLIGHTS**

For the year ended 31 December 2021, total revenue was RMB1,043.0 million as compared with RMB1.4 million for the year ended 31 December 2020; total cost and expenses were RMB1,327.7 million as compared with RMB664.5 million for the year ended 31 December 2020, within which R&D expenses increased by 79.2% to RMB721.6 million from RMB402.8 million for the year ended 31 December 2020. The loss for the year decreased by 83.0% from RMB391.9 million for the year ended 31 December 2020 to RMB66.7 million for the year ended 31 December 2021. Our cash and bank and wealth management products balances increased 65.0% from RMB3,969.6 million for the year ended 31 December 2020 to RMB6,550.5 million for the year ended 31 December 2021.

During the fiscal year, we continued advancing our drug pipeline and business operations, including the following milestones and achievements:

#### **Orelabrutinib**

China National Medical Products Administration (“**NMPA**”) granted Orelabrutinib a market approval on 25 December 2020 for the treatment of patients with relapsed and/or refractory chronic lymphocytic leukemia (“**r/r CLL/SL**”) and the treatment of patients with relapsed and/or refractory mantle cell lymphoma (“**r/r MCL**”). During the Reporting Period, our newly established in-house commercial team generated 宜諾凱® (**Orelabrutinib, BTK inhibitor**) gross revenue of RMB241.2 million.

In December 2021, Orelabrutinib was included in the updated National Drug Reimbursement List (“**NRDL**”) for the treatment of r/r CLL/SLL and r/r MCL.

On 13 July 2021, we entered into a License and Collaboration Agreement for Orelabrutinib for the potential treatment of multiple sclerosis (“**MS**”) with Biogen Inc. (**Nasdaq: BIIB**) (**hereinafter referred to as “Biogen”**). For details, please refer to the announcement of the Company dated 13 July 2021, published on the website of the Hong Kong Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.innocarepharma.com](http://www.innocarepharma.com)). On 22 September 2021, we had received the upfront payment in the amount of USD125 million from Biogen for the said License and Collaboration Agreement. Currently, a global Phase II trial for MS patients is ongoing.

The Phase II trial for systemic lupus erythematosus (“**SLE**”) was completed at the end of 2021. The study showed that Orelabrutinib was safe and well tolerated. Efficacy was demonstrated by remarkable SLE Responder Index (“**SRI**”)-4 response rates in a dose dependent manner. Further development of Orelabrutinib for SLE is warranted and planned.

Further, Orelabrutinib has been included in the 2021 Chinese Society of Clinical Oncology (“**CSCO**”) Diagnosis and Treatment Guidelines for Malignant Lymphoma (the “**Guidelines**”) and is recommended as a Class I treatment for r/r CLL/SLL and r/r MCL, and as an optional treatment for r/r diffuse large B-cell lymphoma (“**DLBCL**”) and primary central nervous system lymphoma (“**pCNSL**”).

There are multiple registrational and exploratory trials ongoing for oncology and auto-immune diseases:

- The NDA for relapsed and/or refractory waldenstrom’s macroglobulinemia (“**r/r WM**”) was accepted by Center for Drug Evaluation (“**CDE**”) in March 2022.
- We expect to submit the NDA for relapsed and/or refractory marginal zone lymphoma (“**r/r MZL**”) in China in the first half of 2022.
- We initiated a Phase III registrational trial in China for the first-line treatment of MCD subtype DLBCL comparing Orelabrutinib in combination with R-CHOP verses R-CHOP.
- We are conducting a Phase III registrational trial for first-line treatment of CLL/SLL in China, comparing Orelabrutinib monotherapy versus rituximab plus chlorambucil.
- We are conducting a Phase III registrational trial for first-line treatment of MCL in China, comparing Orelabrutinib in combination with R-CHOP verses R-CHOP.
- We are exploring the combinational therapy of Orelabrutinib with Gazyva (**obinutuzumab**), an anti-CD20 antibody, for the treatment of B cell lymphoma.
- In the U.S., Phase II registrational trial for r/r MCL is expected to complete patient enrollment in 2022. In June 2021, the U.S. Food and Drug Administration (“**U.S. FDA**” or “**FDA**”) granted Breakthrough Therapy Designation (“**BTB**”) to Orelabrutinib for the treatment of r/r MCL.

- In the U.S., the first patient was enrolled in Phase II trial for MS in the first half of 2021. We started patient enrollment in Europe and China in the third quarter of 2021.
- The IND application for Orelabrutinib for the treatment of primary immune thrombocytopenia purpura (“ITP”) was approved by CDE on 11 August 2021 and the first patient of the Phase II clinical trial was dosed in China on 22 February 2022.
- In February 2022, we received the IND approval of Orelabrutinib by NMPA for starting Phase II clinical trial in Neuromyelitis Optica Spectrum Disorder (“NMOSD”) in China.

## **Other Significant Clinical Stage Assets**

### ***ICP-B04 (Tafasitamab)***

On 17 August 2021, we entered into a Collaboration and License Agreement for the development and commercialization of Tafasitamab, a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody and approved by the U.S. FDA and European Medicine Agency in combination with lenalidomide for the treatment of r/r DLBCL, in Greater China (including Hong Kong, Macau and Taiwan) with Incyte Corporation (**Nasdaq: INCY**) (**hereinafter referred to as “Incyte”**). Tafasitamab is currently the first and the only approved second-time treatment for DLBCL in the U.S..

We are actively pursuing commercialization of Tafasitamab in the Greater China area in a timely manner.

### ***ICP-192 (Gunagratinib)***

In the dose-escalation part of Phase I/II trial, Gunagratinib was demonstrated safe and well-tolerated across all dosage cohorts ranging from 2 to 26mg with no DLT observed. In the dose-escalation trial, the anti-tumor activity of Gunagratinib was observed in head and neck cancer patients carrying FGF/FGFR gene aberrations with an overall response rate (“**ORR**”) of 33.3%. 20mg was selected as the appropriate dosage for Phase II trials. In the Phase II trial, 20mg Gunagratinib showed preliminary efficacy in cholangiocarcinoma patients with 60.0% ORR and 100% disease control rate (“**DCR**”).

In the U.S., we are conducting a Phase I/II dose-escalation trial in advanced solid tumor patients including those with cholangiocarcinoma and head and neck cancer.

### ***ICP-723***

In the Phase I dose escalation study, dosage has been escalated up to 12mg with no DLT observed. 80% ORR was observed in patients with NTRK fusion.

We obtained the U.S. FDA IND approval in 2021 for the treatment of NTRK fusion positive cancers.

### ***ICP-332***

We submitted our novel tyrosine kinase 2 (“**TYK2**”) inhibitor ICP-332 IND application on 15 February 2021 and the NMPA approved the IND of Phase I clinical trial on 18 May 2021. We enrolled the first subject on 16 August 2021 and completed enrollment of the Phase I study at the end of January 2022.

### ***ICP-B02 (CM355)***

ICP-B02 is a CD20xCD3 bispecific antibody co-developed with Keymed Biosciences Inc. (**2162.HK**) (hereinafter referred to as “**Keymed**”) for the treatment of lymphoma. In preclinical studies, it demonstrated stronger T-cell-dependent cellular cytotoxicity (“**TDCC**”) activities with less cytokine release as compared with its key competitors. The IND was approved by the CDE on 17 September 2021 and the dosing of the first patient was completed on 17 January 2022.

At the beginning of September 2021, InnoCare and Keymed signed a strategic cooperation agreement to strengthen R&D collaboration between the two parties, aiming at developing First-in-Class and Best-in-Class innovative large molecular drugs.

### ***ICP-189***

On 19 October 2021, we received IND approval from the NMPA for our SHP2 (“**Src Homology 2 domain containing protein tyrosine phosphatase**”) allosteric inhibitor ICP-189. It is being developed for the treatment of solid tumors as a cornerstone therapy in combinations with other antitumor agents.

On 15 November 2021, we received the IND clearance of ICP-189 by the U.S. FDA for starting clinical trial in the U.S..

### ***ICP-033***

The IND application for ICP-033 was approved by the CDE in June 2021 and we expect to start patient enrollment in 2022. ICP-033 is a novel multi-target Receptor Tyrosine Kinase (“**RTK**”) inhibitor and will be potentially used as monotherapy and/or in combination with immunotherapy and other targeted drugs to treat liver cancer, renal cell carcinoma, colorectal cancer and other solid tumors.

### ***ICP-488***

The IND application was approval by CDE on 22 March 2022, and we anticipate the first subject enrollment in the first half of 2022.

## **IND-Enabling Stage Drug Candidates**

### ***ICP-490***

ICP-490 is a highly potent orally bioavailable next-generation CRBN modulator that modulates the immune system and other biological targets.

We plan to submit the IND application for ICP-490 in the first half of 2022.

### ***ICP-B05 (CM369, newly disclosed)***

ICP-B05 is an anti-CC chemokine receptor 8 (“**CCR8**”) monoclonal antibody, a potential first-in-class drug co-developed by InnoCare and Keymed as a monotherapy or in combination with other therapies for the treatment of various cancers. It has the potential to deliver optimal tumor targeted Treg depletion and be more specific in anti-tumor activity than other immunotherapies.

In China, we anticipate to submit the IND application in the second quarter of 2022.

### ***ICP-248***

ICP-248 is a novel, orally bioavailable B cell lymphoma-2 (“**BCL-2**”) selective inhibitor.

We expect to submit the IND application in China in the first half of 2022.

### ***ICP-915***

ICP-915 is a highly potent, selective small molecule inhibitor against the G12C mutant form of Kirsten Rat Sarcoma (“**KRAS**”) viral oncogene homologue.

Currently, ICP-915 is at the IND enabling stage.

### ***ICP-B03***

ICP-B03 is a tumor-conditional pro-interleukin-15 (“**IL-15**”) targeting and changing immune cells inside tumor microenvironment. IL-15 is a cytokine that stimulates important anti-tumor immune cells, such as CD8+ T cells and Natural Killer (“**NK**”) cells.

We plan to submit the IND application for ICP-B03 to the CDE in early 2023.

## **Other Events**

On 8 February 2022, our Company was notified by the relevant shareholders that, during December 2021 to January 2022, two substantial shareholders of our Company purchased an aggregate of approximately 13 million shares of the Company (the “**Shares**”), via on-market transactions.

Further, certain shareholders (including those who are Directors and/or is a member of the senior management) of the Company have undertaken on a voluntary basis to be subject to lock-up undertakings (the “**Lock-up Undertakings**”), with respect to their direct and indirect interest in the Shares, effective from the date of the announcement dated 8 February 2022. The number of shares held subject to the lock-up undertakings was 678,495,972, which amounted to approximately 45.24% of the total issued capital of the Company at the relevant time and the last day of the Lock-up Undertakings will be 7 August 2022.

On 13 September 2021, our Company announced that among other RMB Share Issue application materials submitted to and accepted by the Shanghai Stock Exchange, the full text of the application proof of the prospectus in relation to the RMB Share Issue (“**RMB Share Prospectus**”) and the relevant appendices were published by the Company in Chinese only on the websites of the Shanghai Stock Exchange ([www.sse.com.cn](http://www.sse.com.cn)), the Hong Kong Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www. Innocarepharma.com/](http://www.Innocarepharma.com/)).

## **FINANCIAL HIGHLIGHTS**

### **Revenue**

Our revenue increased from RMB1.4 million for the year ended 31 December 2020 to RMB1,043 million for the year ended 31 December 2021, which was primarily attributable to (i) the receipt of the license-out upfront payment from Biogen and the (ii) commencement of the sales of Orelabrutinib.

### **Other Income and Gains**

Our other income and gains decreased from RMB271.3 million for the year ended 31 December 2020 to RMB217.9 million for the year ended 31 December 2021, primarily attributable to (i) RMB51.2 million decrease in foreign exchange gain from RMB108.3 million in 2020 to RMB57.1 million in 2021 due to the unrealized exchange gains resulting from our overseas companies’ RMB exchanging to its functional currency, USD; (ii) RMB38.3 million increase in bank interest income from RMB96.8 million in 2020 to RMB135.1 million in 2021; and (iii) RMB48.1 million decrease in recognized government grants from RMB64.4 million in 2020 to RMB16.3 million in 2021.

## **Total Expenses**

Our total expense, including selling and distribution expenses, research and development costs, and administrative expenses, increased from RMB560.4 million for the year ended 31 December 2020 to RMB1,159.9 million for the year ended 31 December 2021, primarily due to the expansion of our clinical trials, the increase in license-in expense, and increase of personnel cost. Such increase was mainly resulted from (i) RMB70.9 million increase of direct clinical trial and third-party contracting cost from RMB96.7 million to RMB167.6 million; (ii) RMB263.7 million increase of license-in and collaborative R&D expenses from RMB9.3 million to RMB273.0 million; (iii) RMB144.2 million increase in employee cost from RMB140.4 million to RMB284.6 million.

## **Loss for The Year**

As a result of the above factors, and taking into account of (i) a decrease in loss due to fair value change of convertible redeemable preferred shares from a loss of RMB69.2 million in 2020 to nil in 2021 due to the Company's Hong Kong listing in the first half of 2020, and (ii) an increase in loss due to the fair value change of convertible loan from a loss of RMB32.4 million for the year ended 31 December 2020 to a loss of RMB51.0 million for the year ended 31 December 2021, (iii) an increase of RMB46.6 million in income tax expense mainly due to the withholding tax from the license-out revenue, the loss for the year decreased from RMB391.9 million for the year ended 31 December 2020 to RMB66.7 million for the year ended 31 December 2021.

## 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 – two large 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 the market during the Reporting Period. 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 in identifying novel targets and developing therapies with global breakthrough potential.

We are well underway of building a leading hema-oncology franchise with (i) the core self-developed Orelabrutinib as a backbone therapy, (ii) the only U.S. FDA approved anti-CD19 antibody Tafasitamab for r/r DLBCL, (iii) multiple pipeline drugs that cover almost all important hema-oncology targets such as CD20xCD3, BCL-2 and E-3 ligase, and (iv) a well established and focused commercialization platform in China.

For the autoimmune diseases, we partnered with the global neurology leader Biogen in MS. Recently, we completed SLE Phase II trial in China and are actively pursuing further development of Orelabrutinib in SLE. We are also exploring Orelabrutinib for the treatment of ITP and NMOSD in Phase II trials. With the addition of our two TYK2 inhibitors (ICP-332 and ICP-488), we are well-positioned to provide oral drug solutions for substantial unmet clinical needs in autoimmune diseases.

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, while our rapidly growing and maturing early-stage pipeline including ICP-033, ICP-189, ICP-B05 ICP-915 and ICP-B03 targeting novel targets such as SHP2 and CCR8 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.

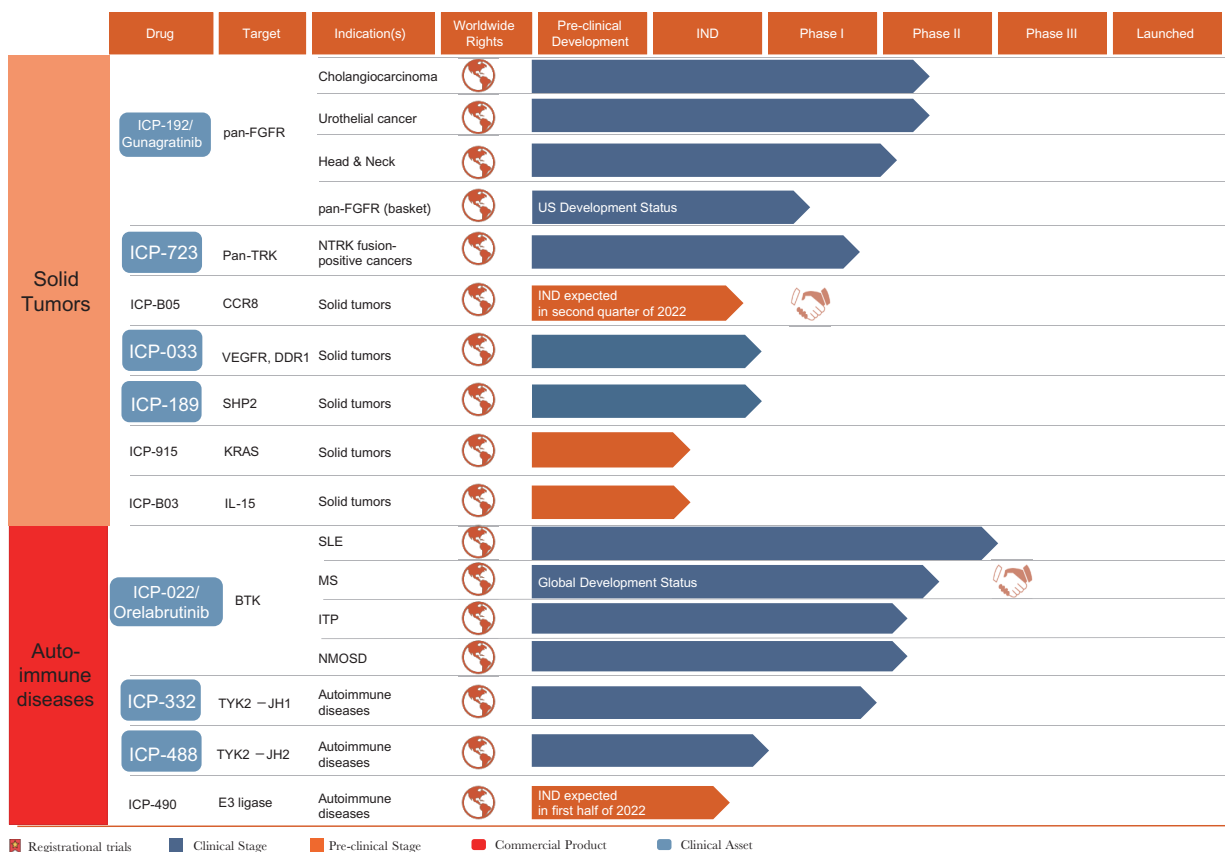
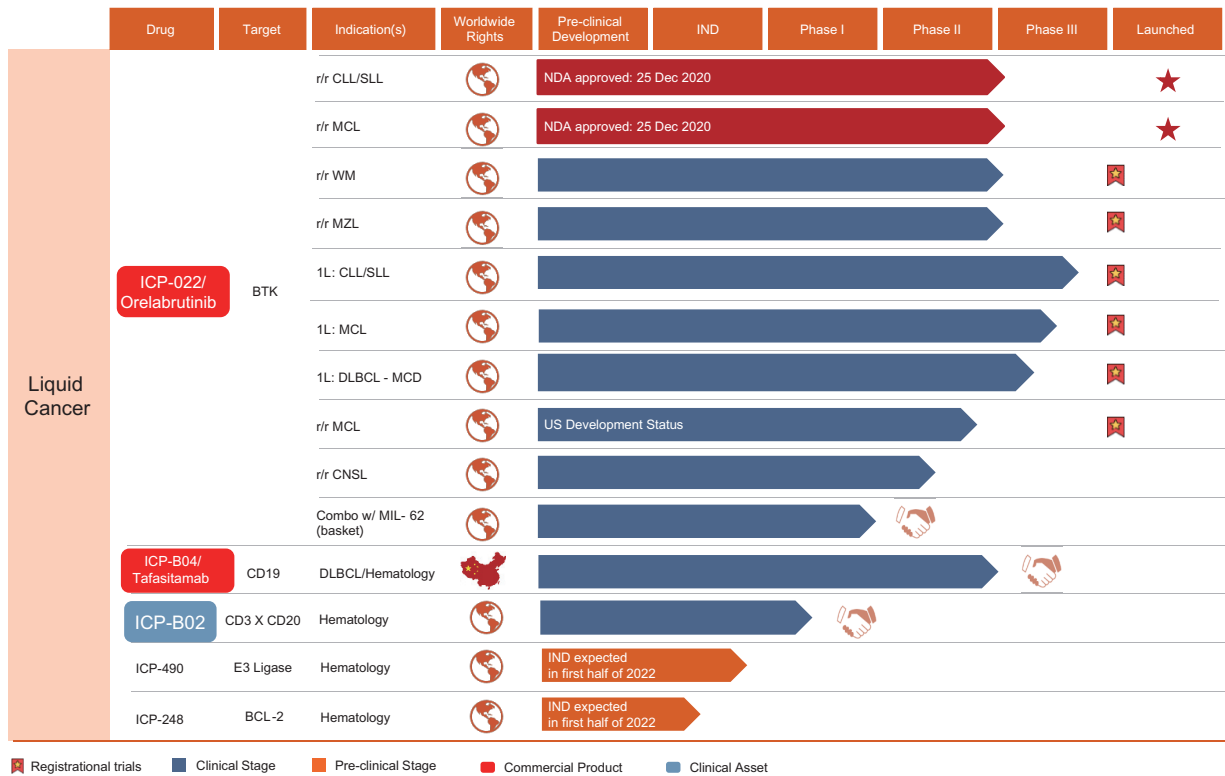
With a proven excellency in small molecule R&D, we are establishing our internal biological drug R&D capability through internal and external efforts. We are also actively considering other new drug modalities such as PROTAC, ADC, molecule glue, and etc.

With two significant business development deals struck in 2021, our business development team is well positioned to continue maximizing the value of our internal pipeline and strengthening our platform through in-licensing and out licensing deals.



## Product Pipeline

As of the date of this announcement, we have built a robust pipeline that includes 1 commercial product with 2 approved indications and additional 6 registrational trials, 10 clinical stage assets, over 30 trials ongoing globally, and another 4 to 5 IND enabling stage candidates. Our current pipeline drugs cover a variety of novel and validated therapeutic targets and drug modalities including monoclonal antibodies, bispecific antibodies, and small molecules across oncology and autoimmune diseases.



## BUSINESS OVERVIEW

In 2021, we continued to make significant progresses with respect to our drug pipeline development, commercialization, and business development, including the following milestones and achievements:

### Orelabrutinib Commercialization Achievements and Milestones

宜諾凱® (Orelabrutinib, BTK inhibitor), our first commercialized product, a highly selective, irreversible BTK inhibitor received approval from the NMPA in two indications: (i) the treatment of patients with r/r CLL/SLL; and (ii) the treatment of patients with r/r MCL. During the fiscal year 2021, we successfully launched 宜諾凱® (Orelabrutinib) in January 2021 and achieved RMB241.2 million in gross revenue.



(宜諾凱®, Orelabrutinib, BTK inhibitor)

In December 2021, 宜諾凱® (Orelabrutinib) was included in China’s NRDL. We also established a national sales network for 宜諾凱® (Orelabrutinib) with an in-house commercial team of ~250 experienced members. Our sales network rapidly penetrated to 260+ cities, covering 1,000+ leading hospitals and 5,000+ doctors throughout China as of 31 December 2021. We expect that the NRDL inclusion and our strengthened commercialization capabilities will enable us to achieve broadened access to patients and accelerated market penetration in 2022 and beyond.

宜諾凱® (Orelabrutinib) was included in the 2021 CSCO Diagnosis and Treatment Guidelines for Malignant Lymphoma (the “**Guidelines**”) and is recommended as a Class I treatment for r/r CLL/SLL and r/r MCL, and as an optional treatment for r/r DLBCL and pCNSL.

## **Orelabrutinib Business Development**

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 Agreement, Biogen will have exclusive rights to Orelabrutinib in the field of MS worldwide and in certain autoimmune diseases outside of China (including Hong Kong, Macau and Taiwan), while our Company will retain exclusive worldwide rights to Orelabrutinib in the field of oncology and certain autoimmune diseases in China (including Hong Kong, Macau and Taiwan).

On 22 September 2021, we received the upfront payment in the amount of USD125 million from Biogen. In addition, we are eligible to receive up to USD812.5 million in potential development milestones and potential commercial payments should the collaboration achieve certain development, commercial milestones and sales thresholds. We are also eligible to receive a tiered royalties in the low to high teens percentage rate on potential future net sales of any product resulting from the collaboration.

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

## **Summary and Updates of Orelabrutinib Clinical Trials and Data**

### **Orelabrutinib for Hema-oncology Diseases**

As at the date of this announcement, we have dosed over 500 patients across all of our clinical trials of Orelabrutinib. 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  $\geq 3$ ) of atrial fibrillation case was reported to date.

### **Orelabrutinib for r/r CLL/SLL**

This is an open-label, multicenter, Phase II study to evaluate the safety and efficacy following 150 mg oral daily administration of Orelabrutinib in r/r CLL/SLL patients. A total of 80 patients with r/r CLL/SLL were enrolled. Our latest data were disclosed at the 63<sup>rd</sup> American Society of Hematology (“**ASH**”) Annual Meeting (11-14<sup>th</sup> December 2021, Atlanta, Georgia, U.S.A.). The median follow-up time was 33.1 months, with 67.5% remaining on treatment. The overall response rate (“**ORR**”) was 93.8 % with 26.3% 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 30-month DOR and PFS were 67.2% and 69.7%, respectively by investigator assessment.

Orelabrutinib showed a significant higher CR/CRi rate in r/r CLL/SLL in comparison with other BTK inhibitors at a similar median follow-up period.

Extended follow-up demonstrated that there were no emerging safety concerns. Similar to the previously reported safety results, most AEs were mild to moderate.

### **Orelabrutinib for r/r MCL**

A Phase II open-label, multicenter, two stage 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 23 months.

The efficacy results were evaluated by investigators. According to the protocol analysis, among the 106 patients, 106% ORR and 93.9% disease control rate were achieved. The CR-rate was 34.3% when measured with the conventional computerized tomography (“CT”) method.

For Orelabrutinib’s 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  $\geq 3$ ) of any cause was thrombocytopenia. No treatment related Grade 3 or above GI toxicity, cardio toxicity or severe bleeding were observed. Compared to the safety data of a median follow up of 10.5 months, the safety profiles were essentially the same. These results suggested that safety events primarily occurred during early stage of treatment and appeared less frequently with continued Orelabrutinib treatment.

In conclusion, Orelabrutinib has shown high efficacy in treating patients with r/r MCL. Orelabrutinib was safe and well tolerated with no treatment related Grade 3 or higher diarrhea, atrial fibrillation/flutter or severe bleeding in this study. This is an ongoing study, and we will continue to evaluate Orelabrutinib as a treatment for r/r MCL. Results of prolonged treatment is expected to produce a higher rate in depth of response while maintaining the safety profile.

### **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 MYD88<sup>L265P</sup> 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 is aimed 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 13.67 months, MRR was 78.7% as assessed by investigator. ORR was 87.2%. The estimated 12-month DOMR was 91.3%. The estimated 12-month PFS and OS were 89.3% and 93.6%, respectively. The median PFS and median OS have 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  $\geq 3$  diarrhea.

On 14 March 2022, the CDE accepted our supplemental NDA application for Orelabrutinib for the treatment of patients with r/r WM.

### **Orelabrutinib for r/r MZL**

This is a multicenter, open-label study to evaluate the safety and efficacy of ICP-022 in patients with r/r MZL. The primary endpoint of this study is efficacy measured by ORR by the independent review board (“**IRC**”) according to the 2014 International Working Group NHL. Secondary endpoints include PFS, OS, DOR and safety, and etc. As of 6 November 2021, a total of 32 sites participated in this study and enrollment was completed.

Currently, the study is ongoing with efficacy and safety follow up.

### **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 47 sites in China. As of 28 February 2022, a total of 74 patients were enrolled in this study. The study is ongoing as at the date of this announcement.

### **Orelabrutinib for 1L MCL**

This is a randomized, open-label, multi-center, Phase III study of Orelabrutinib in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (“**R-CHOP**”) vs. R-CHOP in patients with treatment-naive mantle cell lymphoma. The primary endpoint is to evaluate the PFS evaluated by the IRC according to the 2014 International Working Group Criteria for Non-Hodgkin Lymphoma (“**iwNHL**”). As at the date of this announcement, the study is recruiting patients in 6 active sites in China.

### **Orelabrutinib for 1L DLBCL – MCD Subtype DLBCL**

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. As at the date of this announcement, the study is at the site start-up stage.

Approximately 40% DLBCL patients will eventually become refractory/relapsed. To that, the heterogeneous genetic aberration background is considered as 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- $\kappa$ B activation which indicates this patient sub-group might respond well to BTK inhibitors. The pre-clinical model has also proved 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. 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.

## **Orelabrutinib and Antibody Combination Therapies**

Over the last decade, BTK inhibitor ibrutinib has been validated as an effective treatment against B cell malignancies. Its relatively mild safety profile compared to other chemo – and target-therapeutic agents also makes it a plausible combinatory partner with anti-CD20 antibody treatment to ultimately achieve chemo-free regimens. These efforts have resulted in the U.S. FDA approvals of ibrutinib and rituximab for WM in 2018; ibrutinib and obinutuzumab (“**Gazyva**”) for the first line CLL in 2019; and ibrutinib and rituximab for the first line CLL/SLL in 2020.

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, antibody-dependent cellular phagocytosis (“**ADCP**”), and direct apoptosis induction; but also to avoid significant antagonisms of the combo partners. However, the off-target inhibition of ibrutinib on interleukin-2 (IL-2)-inducible T cell kinase (“**ITK**”) may lead to 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 obinutuzumab (Gazyva), retain fully functional ADCC and 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.

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.

### **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 excellent target selectivity and good safety profile, we are also evaluating it as a novel therapy for the treatment of autoimmune diseases.

## **Orelabrutinib for MS**

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 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 are 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. With the ability to cross the blood brain barrier, Orelabrutinib has the potential to inhibit B cell and myeloid cell effector functions in the central nervous system ("CNS"), and may provide a clinically meaningful benefit in all forms of MS.

***For a detailed overview of the said strategic collaboration with Biogen Inc., please see our announcement dated 13 July 2021 published on the website of the Stock Exchange.***

### **Current Status**

We have initiated a global Phase II trial for MS in the U.S., Europe and China. It is a randomized, double-blind, placebo-controlled Phase II clinical study to evaluate the use of Orelabrutinib in patients with relapsing-remitting multiple sclerosis ("RRMS") regarding its efficacy, safety, tolerability, pharmacokinetics and biological activity. Currently, the Phase II patient enrollment is ongoing through global clinical sites within five countries.

## **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.

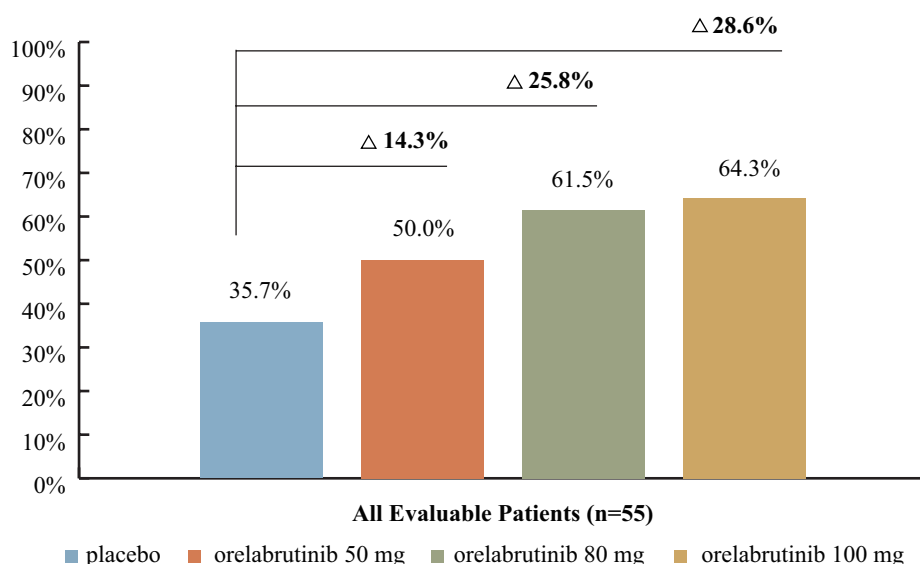
### **Current Status**

In China, Orelabrutinib Phase II trial for SLE was completed at the end of 2021.

The Phase II trial evaluated 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 all evaluable patients treated with Orelabrutinib. The SLE Responder Index ("SRI")-4 response rates at 12-week were 35.7%, 50%, 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.

## SRI-4 response at 12 weeks



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 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 to control the disease activity in SLE patients. The oral administration advantages are better than the recently approved SLE drugs. Based on the Phase II results, the protocol for further development of Orelabrutinib for SLE is being drafted.

### 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 with excellent safety profile, has the potential to become a novel treatment option to ITP patients.

### **Current Status**

The IND application for Orelabrutinib for the treatment of ITP was approved by CDE on 10 August 2021. On 22 February 2022, the first patient of the Phase II clinical trial has been dosed in China.

According to publicly disclosed data at ASH 2021 (*Yu T, Wang L, Ni X, et al. Blood (2021) 138 (Supplement 1): 3172*), Orelabrutinib significantly inhibited the expression of the activation markers CD69 and CD86 of the BCR signaling pathway on B cells, in a vitro study utilizing peripheral blood of ITP patients.



In the active ITP murine models, platelet count was significantly higher in Orelabrutinib treated mice than that of control mice at days 14, 21, 28 after splenocyte transfusion (*Yu T, Wang L, Ni X, et al. Blood (2021) 138 (Supplement 1): 3172*). The proportion of plasma cells and GL-7+ germinal center cells in splenocytes, and the frequency of total B cells in peripheral blood leukocytes were all lower in mice treated with Orelabrutinib than that of the control group (*Yu T, Wang L, Ni X, et al. Blood (2021) 138 (Supplement 1): 3172*).

In summary, Orelabrutinib could effectively suppress the activation and differentiation of B cells in vitro and in vivo, thus alleviate the thrombocytopenia in active ITP murine models.

### **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 age-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 are not completely clear. At present, it 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 like Orelabrutinib hold high potential to become a novel therapy for NMOSD.

### **Current Status**

In February 2022, we received the IND approval of Orelabrutinib by NMPA for starting NMOSD Phase II clinical trial in China.

### ***ICP-B04 (Tafasitamab)***

On 17 August 2021, we entered into a Collaboration and License Agreement with Incyte for the development and commercialization of Tafasitamab, a humanized Fc-modified cytolytic CD-19 targeting monoclonal antibody, 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 autologous stem cell transplant (“**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 is currently the first and the only 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 antibody has the potential to become another fundamental therapy for B-NHL. In RE-MIND2 trial, a retrospective cohort analysis, Tafasitamab plus lenalidomide demonstrated superior efficacy compared to R2 regimen.

We paid Incyte US\$35 million upfront fee during the Reporting Period 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 ongoing 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 antibody, is critical to solidifying our long-term strategy of developing a leading hema-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.***

Tafasitamab offers possibility and flexibility in combination with Orelabrutinib and our other assets for the treatment of B-cell malignancy.

In August 2021, we had started discussions with the Health Commission and Medical Product Administration of Hainan Province under the early access program in Boao Lecheng International Medical Tourism Pilot Zone, and we anticipate issuing the first prescription in the first half of 2022. We intend to submit the NDA applications to local regulatory bodies in Hong Kong and Macau in 2022.

The IND application for the bridging study was accepted by CDE in March 2022.

### ***ICP-192 (Gunagratinib)***

Gunagratinib is a potent and highly selective pan-FGFR (fibroblast growth factor receptors) 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. As Gunagratinib is currently one of the most advanced clinical stage pan-FGFR inhibitors being developed in China, we believe we are well positioned to capitalize this market opportunity.

***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.

Gunagratinib is currently undergoing several Phase I/II clinical studies in China and the U.S.. In China, in the dose-escalation part of Phase I/II trial, Gunagratinib was demonstrated safe and well-tolerated across all dosage cohorts ranging from 2 to 26mg with no DLT observed. In the dose-escalation trial, anti-tumor activity of Gunagratinib was also observed in head and neck cancer patients carrying FGF/FGFR gene aberrations with an overall response rate (“**ORR**”) of 33.3%.

20mg was selected as the appropriate dosage for Phase II trials. In the Phase II trial, 20mg Gunagratinib showed preliminary efficacy in cholangiocarcinoma patients with 60.0% ORR and 100% disease control rate (“**DCR**”).

As of 13 January 2022, among the 5 patients who have completed at least one tumor assessment, the overall response rate (ORR) was 60.0%, including 2 patients with confirmed partial response (“**PR**”) and 1 patient with unconfirmed partial response (“**uPR**”). The DCR was 100%.

### Best of Response-CCA (FAS)

	<b>20mg</b>
N (completed at least one tumor assessment)	5
CR	0
PR	2 (40%)
uPR	1 (20%)
SD	2 (40%)
PD	0
ORR(CR+PR), n (%)	2 (40%)
ORR(CR+PR+uPR), n (%)	3 (60%)
DCR(CR+PR+uPR+SD), n (%)	5 (100%)

We are also progressing Gunagratinib in another Phase II trial for urothelial cancers, which is currently under patient recruitment.

At the beginning of 2022, we initiated a basket trial for solid tumor focusing on head and neck cancer with FGF/FGFR gene aberrations. The patient with esophagus cancer, gastric cancer, breast cancer and other solid tumor with FGF/FGFR gene aberrations will be enrolled as well.

On 17 June 2021, Gunagratinib was granted the Orphan Drug Designation for the treatment of cholangiocarcinoma by the U.S. FDA. In the U.S., we are conducting Phase I/II trial with dose escalation in advanced solid tumors and dose expansion in cholangiocarcinoma and head and neck cancer.

### ICP-723

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 dramatic responses in patients with TRK gene fusions, however, duration of response was limited due to 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.

## **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.

## **Current Status**

We are currently conducting a Phase I clinical trial in China to assess the safety, tolerability, and Pharmacokinetic (“**PK**”) of ICP-723 in advanced solid tumor patients and to evaluate the preliminary anti-tumor activity of ICP-723 in patients with NTRK fusions.

As of 11 February 2022, a total of 17 patients in Phase I dose-escalation trial were treated with ICP-723 at doses of 1 mg QD to 8 mg QD. There is no DLT observed in the 6 dose groups. Most AEs were manageable and Grade 1-2. The plasma exposure of ICP-723 increased in a dose proportional manner across all the dosage cohorts.

Five of 17 patients were considered as NTRK gene fusion positive. Among the 5 patients with NTRK fusion, the overall response rate (“**ORR**”) was 80% (4 patients with partial response (“**PR**”)), and the disease control rate (“**DCR**”) was 100%.

Therefore, ICP-723 is safe and well-tolerated in patients with advanced solid tumors. Encouraging clinical efficacy including intracranial activity was demonstrated in patients with NTRK gene fusion in various tumor types. Enrollment in Phase I is ongoing until the final RP2D is determined, then Phase II trial will be conducted in patients with defined gene alterations.

In the U.S., we obtained the IND approval at the end of August 2021 for the treatment of NTRK fusion positive cancers and intend to start the Phase I clinical trial in the U.S. in 2022.

## **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, atopic dermatitis, 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 non-selective JAK inhibitors. Thus, by selective inhibition of TYK2, ICP-332 may become a potential therapy for multiple autoimmune diseases with better safety profiles.

## **Current Status**

On 18 May 2021, NMPA 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 the middle of March 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-322 were tested in the 80 mg cohort.

ICP-332 demonstrated dose proportionality of the PK parameters (C<sub>max</sub> and AUC<sub>last</sub>) 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.

Currently, a Phase II study in patients with autoimmune disease is being planned based on the data of safety, PK/PD, and biomarkers in the Phase I study.

### **ICP-B02 (CM355)**

ICP-B02 is a CD20xCD3 bispecific antibody co-developed with Keymed for the treatment of lymphoma. 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. We established a 50:50 joint venture with Keymed in August 2018 for the discovery, development, and commercialization of biologics. In June 2020, we entered into a license and collaboration agreement, under which Keymed granted us an exclusive license for 50% ownership of CM355 (ICP-B02).

The IND application for ICP-B02 was approved by the CDE on 17 September 2021 and the dosing of the first patient was completed on 17 January 2022.

### **ICP-189**

ICP-189 is a potent oral allosteric inhibitor of SHP2 with excellent selectivity over other phosphatases. It is being developed for the treatment of solid tumors as a cornerstone therapy in combinations with other antitumor agents. SHP2 is a non-receptor protein tyrosine phosphatase involved in mediating RAS signaling pathway and immune checkpoint pathway for the regulation of cellular proliferation and survival.

In *in-vivo* efficacy studies, ICP-189 demonstrated significant anti-tumor effects in various xenograft models. It is possible for ICP-189 to be synergistic with target therapies (KRAS, MEK) as well as IO agent ie. PD-1.

On 19 October 2021, we received IND approval from the NMPA for ICP-189.

On 15 November 2021, the IND clearance of ICP-189 was granted by the FDA for starting clinical trial in the U.S..

### **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. Pre-clinical studies have shown that ICP-033 exhibits strong antitumor 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.

The IND application for ICP-033 was approved by the CDE in June 2021 and we expect initiating the patient enrollment in 2022.

### **ICP-488**

ICP-488 is a small molecule binder 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 the TYK2 JH2 domain, blocks IL-23, IL12, type 1 IFN and other inflammatory cytokine receptors. We intend to develop ICP-488 for the treatment of inflammatory diseases such as psoriasis and inflammatory bowel disease (“**IBD**”).

The IND application was approval by CDE on 22 March 2022 and we plan to initiate the Phase I trial in the first half of 2022.

## **IND-ENABLING STAGE DRUG CANDIDATES**

### **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. In *in-vivo* efficacy studies, ICP-490 demonstrated significant anti-tumor effects in various multiple myeloma (“**MM**”) xenograft models. By specifically binding to CRL4<sup>CRBN</sup>-E3 ligase complex, it induces ubiquitination and degradation of transcription factors including Ikaros and Aiolos. It might overcome acquired resistance against earlier generations of CRNB modulators while improving the antiproliferative effects. As a small molecule glue platform, clinically, ICP-490 may be used for the treatment of patients with relapsed/refractory multiple myeloma, DLBCL and autoimmune diseases such as systemic lupus erythematosus.

We are currently in pre-IND communications with the NMPA and plan to submit the IND application for ICP-490 in the first half of 2022.

### **ICP-B05 (CM369, newly disclosed)**

CM369 is an anti-CC chemokine receptor 8 (“**CCR8**”) monoclonal antibody, a potential first-in-class drug co-developed 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**”). CM369 binds to CCR8 on Tregs and eradicates immunosuppressive Tregs through ADCC to augment the anti-tumor immunity in TME while preserving peripheral homeostasis. CM369 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.

We plan to file the IND application to the CDE in the second quarter of 2022.

### **ICP-248**

ICP-248 is a novel, orally bioavailable B-cell lymphoma-2 (“**BCL-2**”) selective inhibitor. BCL2 is an important part of apoptotic pathway and is overexpressed in a variety of hematologic malignancies. BCL-2 inhibitors have shown proven 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.

We expect to file the IND application for ICP-248 to the CDE in the middle of 2022.

### **ICP-915**

ICP-915 is a highly potent, selective small molecule inhibitor against the G12C mutant form of KRAS. Gain-of-function mutations of KRAS have long been identified as the most prominent oncogenic drivers in about 30% of human cancers, including KRAS G12C mutation in approximately 13% of NSCLCs.

ICP-915 is a covalent KRAS G12C inhibitor, binding to the mutant cysteine residues specifically and irreversibly, thus preventing activation of KRAS. ICP-915 has high cellular potencies and superior PK profiles in various preclinical animal species, which led to its better efficacies in KRAS G12C mutant xenograft models. ICP-915 may be developed as a cornerstone molecule for combinatory treatments of KRAS mutant solid tumors by tackling multiple modules of the RTK-RAS-MAPK signaling pathway combining with our other receptor tyrosine kinase (“**RTK**”) inhibitors (ICP-192, ICP-033) or SHP2 inhibitor (ICP-189).

We expect to file the IND application for ICP-915 to the CDE in the second half of 2022 and to combine it with ICP-189 (SHP2) to treat indications in the solid tumor therapeutics.

## ICP-B03

ICP-B03 is a tumor-conditional pro-interleukin-15 (“**IL-15**”) targeting and changing immune cells inside tumor microenvironment. IL-15 is a cytokine that stimulates important anti-tumor immune cells, such as CD8+ T cells and Natural Killer (“**NK**”) cells. ICP-B03 has shown strong activities in activating and proliferating immune cells without activating inhibitory regulatory T cells (“**Tregs**”), leading to a potent and durable anti-tumor response. Preclinical studies of ICP-B03 in MC38 colon cancer models have shown much longer survival rates compared to those of wild mouse models. ICP-B03 has the potential to improve anti-tumor efficacies of existing therapies, such as immune checkpoint inhibitors, chemotherapies etc.

We expect to submit the IND application for ICP-B03 to the CDE in 2023.

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

## Manufacturing

We have built our own in-house manufacturing facilities and commercialization capabilities. Our 50,000 m<sup>2</sup> Guangzhou manufacturing facility complies with GMP requirements of the U.S., Europe, Japan and China, and will have an annual production capacity of one billion pills. We have successfully obtained a manufacturing license for the facility.

By the end of December 2021, we accomplished the technology transfer from our contract manufacture organization (“**CMO**”) and started the relevant authorities’ on-site inspections. Currently, we are proceeding to the adjustment and improvement of the pilot mass production. We anticipate completion of the inspections by relevant regulatory authorities and commence our own commercial production of Orelabrutinib in the first half of 2022.

In addition, we plan to expand our manufacturing facilities to provide sufficient capacity for our growing and maturing drug pipeline and to support our continued business expansions. We have started the construction of the second phase of the facility in Guangzhou site that is designed to house an additional 30,000 m<sup>2</sup> production area.

As of 31 December 2021, we obtained a 70,381 m<sup>2</sup> land in Beijing next to our Company headquarter inside the Life Science Park, on which we intend building a landmark R&D center and large molecule production facility. So far, we have finished the conceptional design and expect the construction to be completed in 2025.

## Other Corporate Developments

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 gross proceeds and net proceeds from the issue of the 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. For details of the said subscription, please refer to the announcements of the Company dated 3 February 2021 and 10 February 2021 available at the website of the Stock Exchange. Up to 31 December 2021, the proceeds of the subscription has been utilized in accordance with its intended use as set out in the relevant announcement of the Company.

In the first half of 2021, Dr. Sean Zhang and Dr. Davy Ouyang joined our Company and as Chief Medical Officer and Biology Vice President, respectively.

On 13 September 2021, our Company announced that among other RMB Share Issue application materials submitted to and accepted by the Shanghai Stock Exchange, the full text of the application proof of the prospectus in relation to the RMB Share Issue (“RMB Share Prospectus”) and the relevant appendices were published by the Company in Chinese only on the websites of the Shanghai Stock Exchange ([www.sse.com.cn](http://www.sse.com.cn)), the Hong Kong Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.innocarepharma.com/](http://www.innocarepharma.com/)).

In the second half of 2021, Dr. Nan Gao and Ms. Jessie Wang joined in our Company and as Chief Operation Officer and General Counsel, respectively.

## **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 global clinical trials. 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 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**

Subsequent to 31 December 2021, the following significant events took place:

For the long term value and future prospect of the Company’s principal business of discovering, developing, and commercializing best-in-class and/or first-in-class drugs for the treatment of oncology and autoimmune diseases for the unmet clinical needs, certain shareholders (including those who are also Directors and/or is a member of the senior management) of the Company have undertaken on a voluntary basis to be subject to lock-up undertakings (the “**Lock-up Undertakings**”) made in favour of the Company only, with respect to their direct and indirect interest in the Shares, effective from the date of the announcement dated 8 February 2022. The shares held subject to the lock-up undertakings as at the date of the announcement was 678,495,972, which amounted to approximately 45.24% of the total issued capital of the Company at the relevant time. The last day of the Lock-up Undertakings will be 7 August 2022.

Save as disclosed, no other important events affecting the Company occurred after 31 December 2021 and up to the date of this announcement.

## **FUTURE DEVELOPMENT**

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:

### **Building A Global Leading Franchise in Hema-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 hematology in China and worldwide.

Leveraging the strong uptake of its launch in 2021, we will continue to accelerate the sales of the commercialization of 宜諾凱® (Orelabrutinib) in China subsequent to its inclusion in the NRDL. At this stage, our specialized and experienced sales and marketing team has been expanded to approximately 250 members, which we believe would be sufficient to cover the entire domestic hematology market.

We have initiated a broad clinical program for Orelabrutinib in various B-cell malignancies in China to broaden its indication including: registrational trials of 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. in r/r MCL and actively pursuing potential combination therapy partners to maximize the value of its superior clinical profile in NHL market ex-China.

### **Develop Orelabrutinib in MS Through Partnership with Biogen**

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 be up to US\$48.9 billion by 2030. BTK plays important roles 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 best-in-class BTK inhibitor for MS.

We are working closely with Biogen, the absolute leading player in the global MS market, to quickly move forward our Phase II MS global clinical trials on a timely basis and hopefully to establish Orelabrutinib as the best-in-class BTK inhibitor for MS treatment.

## **Develop Orelabrutinib and Other Potential Candidates for Autoimmune Diseases**

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 II SLE clinical trial, we believe Orelabrutinib could potentially become the first-in-class BTK inhibitor in the treatment of SLE and we are actively planning further development scheme. In addition, 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 atopic dermatitis (“AD”), psoriasis, and IBD. 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.

## **Build 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 initial presence in the field of solid tumor treatment. Our rapidly maturing early-stage pipeline including ICP-033, ICP-189, ICP-915 and ICP-B03 should enable us to provide a competitive treatment solution for a large array of solid tumors for both China and global patients.

## **Continue 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 allow us to fully leverage and capitalize our commercial and manufacturing platform, and those have potential synergies with our current pipeline for combination therapies.

## **Establish 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-B03 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.

## FINANCIAL REVIEW

### Revenue

	Year Ended 31 December			
	2021		2020	
	RMB'000	%	RMB'000	%
	<i>(in thousands, except percentages)</i>			
<b>Revenue from continuing operations</b>				
Net sales of Orelabrutinib	214,666	20.6	–	–
IP transfer and R&D service	828,367	79.4	1,364	100
<b>Total Revenue</b>	<b>1,043,033</b>	<b>100</b>	<b>1,364</b>	<b>100</b>

Our revenue increased from RMB1.4 million in 2020 to RMB1,043.0 million in 2021, which was primarily attributable to: (i) the income of RMB827.0 million from the license-out and collaboration revenue with Biogen for Orelabrutinib; and (ii) the increased net sales of Orelabrutinib of RMB214.7 million, deducted by inventory compensation subsequent to the inclusion of Orelabrutinib into the NRDL.

### Gross Profit and Gross Profit Margin

	Year Ended 31 December			
	2021		2020	
	RMB'000	%	RMB'000	%
	<i>(in thousands, except percentages)</i>			
Net sales of Orelabrutinib	191,008	19.5	–	–
IP transfer and R&D service	786,358	80.5	1,364	100
	<b>977,366</b>	<b>100</b>	<b>1,364</b>	<b>100</b>

As a result of the foregoing, our gross profit increased from RMB1.4 million in 2020 to RMB977.4 million in 2021.

### Segmental Information

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

### Other Income and Gains

Our other income and gains decreased from RMB271.3 million for the year ended 31 December 2020 to RMB217.9 million for the year ended 31 December 2021, primarily attributable to (i) RMB51.2 million decrease in foreign exchange gain from RMB108.3 million in 2020 to RMB57.1 million due to the unrealized exchange gains resulting from our overseas company's RMB exchanging to its functional currency, USD; (ii) RMB38.3 million increase in bank interest income from RMB96.8 million in 2020 to RMB135.1 million in 2021; and (iii) RMB48.1 million decrease in recognized government grants from RMB64.4 million to RMB16.3 million.

### **Research and development costs**

Our research and development costs increased from RMB402.8 million for the year ended 31 December 2020 to RMB721.6 million for the year ended 31 December 2021, primarily due to the expansion of our clinical trials and the increase in license-in expense, offset by a decrease in share-based compensation. Such increase in R&D costs resulted from the following:

	<b>Year Ended 31 December</b>			
	<b>2021</b>		<b>2020</b>	
	<b>RMB'000</b>	<b>%</b>	<b>RMB'000</b>	<b>%</b>
License-in and collaborative R&D expenses	<b>273,026</b>	<b>37.8</b>	9,282	2.3
Direct clinical trial and third-party contracting cost	<b>167,589</b>	<b>23.2</b>	96,700	24.0
Employee cost	<b>136,923</b>	<b>19.0</b>	83,713	20.8
Share-based compensation	<b>39,428</b>	<b>5.5</b>	180,983	44.9
Depreciation and amortisation	<b>21,837</b>	<b>3.0</b>	6,467	1.6
Others	<b>82,781</b>	<b>11.5</b>	25,626	6.4
<b>Research and development costs</b>	<b><u>721,584</u></b>	<b><u>100.0</u></b>	<b><u>402,771</u></b>	<b><u>100.0</u></b>

- (i) RMB263.7 million increase of license-in and collaborative R&D expenses from RMB9.3 million to RMB273.0 million;
- (ii) RMB70.9 million increase of direct clinical trial and third party contracting cost from RMB96.7 million to RMB167.6 million;
- (iii) RMB53.2 million increase of R&D employees cost from RMB83.7 million to RMB136.9 million;
- (iv) RMB141.6 million decrease of share-based compensation from RMB181.0 million to RMB39.4 million; and
- (v) RMB57.2 million increase of other R&D expenses such as trial materials etc., from RMB25.6 million to RMB82.8 million.

### ***Administrative Expenses***

Our administrative expenses increased from RMB89.4 million for the year ended 31 December 2020 to RMB139.8 million for the year ended 31 December 2021, primarily attributable to (i) an increase in employee cost of our administrative personnel from RMB31.2 million to RMB47.0 million; (ii) an increase in share-based compensation from RMB9.7 million to RMB43.0 million; (iii) an increase in professional fees from RMB9.7 million to RMB35.6 million; and (iv) one time decrease in listing expense from RMB24.6 million to Nil.

	Year Ended 31 December			
	2021		2020	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Employee cost	46,964	33.6	31,227	34.9
Share-based compensation	43,017	30.8	9,745	10.9
Professional fees	35,563	25.4	9,661	10.8
Depreciation and amortisation	3,637	2.6	3,458	3.9
Listing expense	–	–	24,589	27.5
Others	10,634	7.6	10,691	12.0
<b>Administrative Expenses</b>	<b>139,815</b>	<b>100.0</b>	<b>89,371</b>	<b>100.0</b>

### ***Selling and Distribution Expenses***

Selling and Distribution expenses increased from RMB68.2 million for the year ended 31 December 2020 to RMB298.5 million for the year ended 31 December 2021, primarily attributable to the commercialization of Orelabrutinib and relevant sales and distribution expenses increased, including (i) an increase in employee cost of our sales and marketing personnel from RMB25.5 million to RMB100.7 million; (ii) an increase in market research and market promotion from RMB16.0 million to RMB126.5 million; (iii) an increase in share-based compensation from RMB21.6 million to RMB44.0 million

	Year Ended 31 December			
	2021		2020	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Market research and market promotion	126,462	42.4	15,964	23.4
Employee cost	100,712	33.7	25,487	37.4
Share-based compensation	43,999	14.7	21,550	31.6
Others	27,290	9.2	5,207	7.6
<b>Selling and Distribution Expenses</b>	<b>298,463</b>	<b>100.0</b>	<b>68,208</b>	<b>100.0</b>

### ***Fair value changes of convertible redeemable preferred shares***

Our fair value changes of convertible redeemable preferred shares is Nil for the year ended 31 December 2021 comparing to RMB69.2 million for the year ended 31 December 2020, primarily attributable to the preferred shares converting to ordinary shares due to the IPO in March 2020.

### ***Fair value changes of convertible loan***

Our fair value changes of convertible loan with Guangzhou Kaide Technology Development Co., Ltd increased from RMB32.4 million for the year ended 31 December 2020 to RMB51.0 million for the year ended 31 December 2021.

### ***Finance Costs***

Our finance costs increased from RMB1.1 million in 2020 to RMB2.6 million in 2021, primarily due to the increase of discounted finance fees as requested by IFRS16 as new leases were entered in 2021.

### ***Income tax expense***

Our income tax expense rose mainly because of the withholding tax from the income generated from License and Collaboration Agreement.

### **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:

	<b>As of 31 December</b>	
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>CURRENT ASSETS</b>		
Trade receivables	45,273	152
Prepayments, other receivables and other assets	116,145	120,563
Inventories	9,918	1,878
Financial assets at fair value through profit or loss	317,059	–
Cash and bank balances	5,928,716	3,969,640
<b>Total current assets</b>	<b>6,417,111</b>	<b>4,092,233</b>
<b>CURRENT LIABILITIES</b>		
Trade payables	84,602	5,520
Contract liabilities	6,831	–
Other payables and accruals	204,886	85,454
Deferred income	12,647	6,646
Lease liabilities	20,336	6,833
<b>Total current liabilities</b>	<b>329,302</b>	<b>104,453</b>
<b>NET CURRENT ASSETS</b>	<b>6,087,809</b>	<b>3,987,780</b>

We had net current assets of RMB6,087.8 million as of 31 December 2021, which was primarily attributable to our cash and bank balances of RMB5,928.7 million, prepayments, other receivables and other assets of RMB116.1 million and financial assets at fair value through profit or loss of RMB317.1 million, which was partially offset by other payables and accruals of RMB204.9 million and trade payables of RMB84.6 million.

### ***Trade Receivables***

Our trade receivables mainly consist of the receivables by selling Orelabrutinib and providing R&D services mainly related to the Biogen collaboration. 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:

#### *Within 3 months*

	<b>2021</b> <b><i>RMB'000</i></b>	2020 <i>RMB'000</i>
Receivables from selling Orelabrutinib	<b>20,556</b>	–
Receivables from R&D service	<b>24,717</b>	152
	<b><u>45,273</u></b>	<u>152</u>

The Group's trade receivables are caused by sales of Orelabrutinib and provision of R&D services mainly related to the Biogen collaboration, and our trading terms with customers are mainly on credit, except for new customers, where payment in advance is normally required. The credit period is generally one month, extendable to up to three months for major customers. Each customer has a maximum credit limit. The Group seeks to maintaining strict control over its outstanding receivables and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. In view of the fact that the trade receivables are immaterial and relate to a wide spread of 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 RMB120.6 million as of 31 December 2020 to RMB116.1 million as of 31 December 2021, primarily due to (i) RMB30.3 million decrease in deductible input VAT from RMB47.7 million as of 31 December 2020 to RMB17.4 million as of 31 December 2021; (ii) RMB15.2 million increase in interest receivable from RMB26.2 as of 31 December 2020 to RMB41.4 million as of 31 December 2021; (iii) RMB5.0 million decrease in prepayments from RMB42.5 million as of 31 December 2020 to RMB37.5 million as of 31 December 2021; and (iv) RMB16.3 million increase in other assets from Nil as of 31 December 2020 to RMB16.3 million as of 31 December 2021.

	As of 31 December	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Interest receivable	<b>41,363</b>	26,236
Prepayments	<b>37,532</b>	42,461
Value-added tax recoverable	<b>17,362</b>	47,723
Other assets	<b>16,340</b>	–
Other receivables	<b>3,548</b>	4,143
	<b>116,145</b>	<b>120,563</b>

### ***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 profit or loss, with RMB317.1 million in current assets and RMB304.7 million in non-current assets.

### ***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:

	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	<b>81,697</b>	3,987
3 to 6 months	<b>1,505</b>	382
6 to 12 months	<b>1,257</b>	1,086
Over 12 months	<b>143</b>	65
	<b>84,602</b>	<b>5,520</b>

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 RMB85.5 million as of 31 December 2020 to RMB204.9 million as of 31 December 2021, primarily due to (i) an increase in payable for property, plant and equipment from RMB30.7 million as of 31 December 2020 to RMB47.0 million as of 31 December 2021; (ii) an increase in payroll payables from RMB26.3 million as of 31 December 2020 to RMB41.4 million as of 31 December 2021; and (iii) an increase in sales rebate from Nil as of 31 December 2020 to RMB33.1 million as of 31 December 2021; (iv) an increase in payable for investments in joint ventures from Nil as of 31 December 2020 to RMB20.0 million as of 31 December 2021, arising from the unpaid additional capital injection into the joint venture; (v) an increase in individual income tax and other taxes from RMB1.4 million as of 31 December 2020 to RMB37.4 million as of 31 December 2021.

	<b>As of 31 December</b>	
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Payable for property, plant and equipment	<b>46,956</b>	30,746
Payroll payables	<b>41,406</b>	26,305
Individual income tax and other taxes	<b>37,360</b>	1,401
Sales rebate	<b>33,070</b>	–
Accruals	<b>23,024</b>	23,902
Payable for investments in joint ventures	<b>20,000</b>	–
Others	<b>3,070</b>	3,100
	<hr/>	<hr/>
<b>Other Payables and Accruals</b>	<b>204,886</b>	85,454
	<hr/> <hr/>	<hr/> <hr/>

### ***Indebtedness and finance lease***

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

	<b>As of 31 December</b>	
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>Included in current liabilities</b>		
Lease liabilities	<b>20,336</b>	6,833
	<hr/>	<hr/>
<b>Included in non-current liabilities</b>		
Convertible loan	<b>1,200,564</b>	1,149,550
Long term payables	<b>37,693</b>	–
Lease liabilities	<b>47,442</b>	17,165
	<hr/>	<hr/>
<b>Total indebtedness</b>	<b>1,306,035</b>	1,173,548
	<hr/> <hr/>	<hr/> <hr/>

Our total indebtedness increased from RMB1,173.5 million as of 31 December 2020 to RMB1,306.0 million as of 31 December 2021, mainly due to the increase of lease liabilities, convertible loan and other borrowings.

### ***Deferred income***

Our total deferred income, classified in current-liabilities and non-current liabilities, increased from RMB106.6 million as of 31 December 2020 to RMB136.3 million as of 31 December 2021, mainly due to newly granted government subsidy to Guangzhou InnoCare.

### ***The Property, Plant and Equipment***

The property, plant and equipment increased from RMB306.4 million as of 31 December 2020 to RMB430.1 million as of 31 December 2021, which was mainly caused by increase of Guangzhou InnoCare buildings, plant and machinery.

Guangzhou InnoCare is located at 18 Kangzhao San Road, Huangpu, Guangzhou, China, with a land site and gross floor area of approximately 83,000 m<sup>2</sup> and 65,000 m<sup>2</sup>, respectively. The current construction plan of Guangzhou InnoCare comprises two stages.

### ***Right-of-use of assets***

The right of use assets increased from RMB96.7 million as of 31 December 2020 to RMB136.0 million as of 31 December 2021, which was mainly caused by an increase in lease-in real estates.

### ***Investments in joint ventures***

Our investments in joint ventures increased from RMB1.2 million as of 31 December 2020 to RMB21.4 million as of 31 December 2021, mainly because of additional capital injection into the joint venture.

### ***Other Non-Current Assets***

Other Non-current assets increased from RMB1.0 million as of 31 December 2020 to RMB51.0 million, mainly due to RMB32.0 million increase of prepayment for leasehold land and other increase in prepayment for property, plant and equipment, and database system.

### ***Key Financial Ratios***

The following table sets forth our selected key financial ratio:

	<b>As of</b>	
	<b>31 December</b>	31 December
	<b>2021</b>	2020
Current ratio	<b><u>19.5</u></b>	<b><u>39.2</u></b>

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 increase of other payables from RMB85.5 million as of 31 December 2020 to RMB204.9 million as of 31 December 2021, and an increase in trade payables and from RMB5.5 million as of 31 December 2020 to RMB84.6 million as of 31 December 2021, partially offset by an increase in cash and bank balances from RMB3,969.6 million as of 31 December 2020 to RMB5,928.7 million as of 31 December 2021, and an increase in financial assets at fair value through profit or loss of RMB317.1 million.

## **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.

We currently do not have any plan for material additional external debt financing. 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 over-allotment 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.

As of 31 December 2021, our cash and bank and wealth management products balances were RMB6,550.5 million, as compared to RMB3,969.6 million as of 31 December 2020. The increase was mainly due to the 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**

As at 31 December 2021, we did not hold any significant investments. For the Reporting Period, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

## **GEARING RATIO**

The gearing ratio (calculated as total debt (includes loans and borrowings and convertible loan) divided by total assets and multiplied by 100%) as of 31 December 2021 was 17% (31 December 2020: 24%).

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 2021, except for RMB1,200.1 million of the convertible loan with Guangzhou Kaide Technology Development Co., Ltd. and long-term payable of RMB37.7 million, we did not have any other 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 2021, we did not have any material contingent liabilities and litigations.

## **FOREIGN EXCHANGE RISK**

Our financial statements are expressed in RMB, but certain of our cash and cash equivalents, time deposits, trade and other receivables, and 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.

## **PLEDGE OF ASSETS/CHARGE ON ASSETS**

There was no pledge of the Group's assets as of 31 December 2021.

## **FINAL DIVIDEND**

No dividend was declared and paid by the Group for the year ended 31 December 2021.

## **ANNUAL GENERAL MEETING**

The forthcoming annual general meeting ("AGM") of the Company will be held on Tuesday, 21 June 2022. 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 Thursday, 16 June 2022 to Tuesday, 21 June 2022, 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 Wednesday, 15 June 2022.

## 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.

### AMENDMENTS TO THE ARTICLES OF ASSOCIATION OF THE COMPANY

At the Company's 2021 extraordinary general meeting (the "EGM") held on 21 June 2021, the shareholders passed a special resolution in relation to the amendments to the Articles of Association of the Company (the "Articles of Association"). The adoption of the amended and restated Articles of Association will take effect from the date of listing of the RMB Shares on the STAR Market. For further details of the said amendments to the Articles of Association, please refer to the Company's circular dated 3 June 2021.

### 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:

- Ms. Yeung Ching Man – tendered her resigned as (i) the Company Secretary of the Company (the "Company Secretary") (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 9 February 2021.
- Mr. Wong Keith Shing Cheung – appointed as the Company Secretary, Authorised Representative and Process Agent in replacement of Ms. Yeung Ching Man with effect from 9 February 2021 and resigned with effect from 23 March 2022.
- Ms. Lee Angel Pui Shan – appointed as the Company Secretary, Authorised Representative and Process Agent in replacement of Mr. Wong Keith Shing Cheung with effect from 23 March 2022.
- Dr. Rick Xu – retired from Chief Medical Officer of the Company following a transition period announced on 1 March 2021.
- Dr. Xiang-Yang Zhang – appointed as the Chief Medical Officer of the Company effective on 1 March 2021.
- Mr. Lijun Lin – resigned as a non-executive Director with effect from 31 March 2021.
- Mr. Ronggang Xie – appointed as a non-executive Director with effect from 31 March 2021.

## COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

The Board is committed to achieving high corporate governance standards. The Board believes that high corporate governance standards are essential in providing a framework for the Group to safeguard the interests of shareholders and to enhance corporate value and accountability.

During the year ended 31 December 2021, the Company has complied with all applicable code provisions set out in the CG Code contained in Appendix 14 to the Listing Rules except for the following deviation.

Pursuant to code provision A.2.1 of the CG Code (which has been renumbered as code provision C.2.1 since 1 January 2022), 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;
- (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;
- (iv) 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; and

- (v) 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 and monitor its corporate governance practices to ensure compliance with the CG Code and maintain a high standard of corporate governance practices of the Company.

## **COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTOR OF THE LISTING ISSUERS**

The Company has adopted the Model Code to regulate all dealings by Directors and relevant employees of the Listing Issuers (the “**Model Code**”) as set out in Appendix 10 to the Listing Rules.

Mr. Quanhong Yuan (“**Mr. Yuan**”), a non-executive Director of the Company, filed a notice of disclosure of interest (the “**DI Notice**”) dated 22 February 2022 in relation to an increase of his deemed interests in the Company by 4,208,417 Shares, and the date of relevant event giving rise to the filing of the DI Notice was 8 February 2022. Following an enquiry from the Company, Mr. Yuan confirmed that the dealings as set out in the DI Notice did not take place during the relevant black-out period applicable to the Company’s 2021 interim results from 28 July 2021 to 27 August 2021 and the relevant black-out period applicable to the Company’s 2021 annual result from 24 January 2022 to 25 March 2022 (and subsequently revised to from 22 January 2022 to 23 March 2022). Mr. Yuan also confirmed that he did not take steps to follow the notification requirement under Rule B.8 of the Model Code with respect to any dealings as may be disclosed in the DI Notice, and is currently taking steps to investigate the relevant facts and circumstances giving rise to the filing of DI Notice. The Company will disclose the developments of the investigation in the Annual Report.

Specific enquiries have been made to all the Directors, saved as disclosed above, all the Directors have confirmed that they have complied with the Model Code during the year ended 31 December 2021. No incident of non-compliance of the Model Code by the relevant employees has been noted by the Company during the year ended 31 December 2021.

## **PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES**

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 2021 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 2021. 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 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 2021 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 PROCEEDS

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 2021, HKD686.8 million, or 28% of the net proceeds have been utilized as specified in the below table. The Company intends to use the remaining net proceeds in the manner consistent with that mentioned in the section head “Future Plans and Use of Proceeds” in the Prospectus. The remaining proceeds will be used in the following two years. The completion time of using such proceeds will be determined based on the Company’s actual business needs and future business development.

	Use of proceeds as stated in the Prospectus <i>(in HKD'000)</i> <i>(approximate)</i>	Net proceeds unutilized as of 31 December 2020 <i>(in HKD'000)</i> <i>(approximate)</i>	Actual use of proceeds during 2021 <i>(in HKD'000)</i> <i>(approximate)</i>	Net proceeds unutilized as of 31 December 2021 <i>(in HKD'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	1,007,505	154,391	853,114	The actual amount is expected to be fully utilized by the second half of 2023
25% for our two clinical stage product candidates, ICP-192 and ICP-105	603,917.5	583,760.5	20,122	563,638.5	The amount is expected to be fully utilized by the second half of 2023
15% for the R&D of the six IND-enabling stage candidates in our pipeline and the R&D and in-licensing of new drug candidates	362,350.5	308,572.5	60,157	248,415.5	The amount is expected to be fully utilized by the second half of 2023
10% for working capital and general corporate purposes	241,567	170,414	106,748	63,666	The amount is expected to be fully utilized by the second half of 2023
	<b>2,415,670</b>	<b>2,070,252</b>	<b>341,418</b>	<b>1,728,834</b>	

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. The use of these 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 2021:

	Actual use of proceeds up to 31 December 2021 <i>(in HKD'000)</i> <i>(approximate)</i>	Net proceeds unutilized as of 31 December 2021 <i>(in HKD'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	<u>3,041,440</u>	<u>608,378</u>	<u>2,433,062</u>
			Expected to be fully utilized in three years since 23 March 2021, and subject to, among other things, change of market conditions.

**CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2021**

**CONSOLIDATED STATEMENT OF PROFIT OR LOSS**

*Year ended December 31, 2021*

	<i>Notes</i>	<b>2021</b> <b>RMB'000</b>	2020 <i>RMB'000</i> (Restated)
<b>REVENUE</b>	<i>5</i>	<b>1,043,033</b>	1,364
Cost of sales		<u>(65,667)</u>	<u>–</u>
Gross profit		<b>977,366</b>	1,364
Other income and gains	<i>5</i>	<b>217,938</b>	271,304
Selling and distribution expenses		<b>(298,463)</b>	(68,208)
Research and development costs		<b>(721,584)</b>	(402,771)
Administrative expenses		<b>(139,815)</b>	(89,371)
Other expenses		<b>(1,271)</b>	(1,489)
Fair value changes of convertible redeemable preferred shares	<i>6</i>	–	(69,181)
Fair value changes of convertible loan		<b>(51,014)</b>	(32,374)
Impairment losses on financial assets		<b>(32)</b>	–
Share of losses of joint ventures		<b>(604)</b>	–
Finance costs		<u>(2,642)</u>	<u>(1,139)</u>
<b>LOSS BEFORE TAX</b>		<b>(20,121)</b>	(391,865)
Income tax expense	<i>6</i>	<u>(46,558)</u>	<u>–</u>
<b>LOSS FOR THE YEAR</b>		<u><b>(66,679)</b></u>	<u>(391,865)</u>
Attributable to:			
Owners of the parent		<b>(64,545)</b>	(391,395)
Non-controlling interests		<u>(2,134)</u>	<u>(470)</u>
		<u><b>(66,679)</b></u>	<u>(391,865)</u>
<b>LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT</b>			
– Basic and diluted	<i>8</i>	<u><b>(RMB0.05)</b></u>	<u>(RMB0.40)</u>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended December 31, 2021

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i> (Restated)
<b>LOSS FOR THE YEAR</b>	<b><u>(66,679)</u></b>	<b><u>(391,865)</u></b>
<b>OTHER COMPREHENSIVE LOSS</b>		
Other comprehensive loss that may not be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>(89,453)</u>	<u>(324,100)</u>
<b>OTHER COMPREHENSIVE LOSS FOR THE YEAR, NET OF TAX</b>	<b><u>(89,453)</u></b>	<b><u>(324,100)</u></b>
<b>TOTAL COMPREHENSIVE LOSS FOR THE YEAR</b>	<b><u>(156,132)</u></b>	<b><u>(715,965)</u></b>
Attributable to:		
Owners of the parent	<u>(153,998)</u>	<u>(715,495)</u>
Non-controlling interests	<u>(2,134)</u>	<u>(470)</u>
	<b><u>(156,132)</u></b>	<b><u>(715,965)</u></b>

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
**31 December 2021**

	<i>Notes</i>	<b>2021</b> <b>RMB'000</b>	2020 <b>RMB'000</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		<b>430,081</b>	306,398
Right-of-use assets		<b>135,999</b>	96,733
Goodwill		<b>3,125</b>	3,125
Other intangible assets		<b>34,166</b>	37,017
Investments in joint ventures		<b>21,423</b>	1,159
Financial assets at fair value through profit or loss		<b>304,675</b>	–
Other non-current assets		<b>50,951</b>	1,045
Total non-current assets		<b>980,420</b>	445,477
<b>CURRENT ASSETS</b>			
Inventories		<b>9,918</b>	1,878
Trade receivables	9	<b>45,273</b>	152
Prepayments, other receivables and other assets		<b>116,145</b>	120,563
Financial assets at fair value through profit or loss		<b>317,059</b>	–
Cash and bank balances		<b>5,928,716</b>	3,969,640
Total current assets		<b>6,417,111</b>	4,092,233
<b>CURRENT LIABILITIES</b>			
Trade payables	10	<b>84,602</b>	5,520
Contract liabilities		<b>6,831</b>	–
Other payables and accruals		<b>204,886</b>	85,454
Deferred income		<b>12,647</b>	6,646
Lease liabilities		<b>20,336</b>	6,833
Total current liabilities		<b>329,302</b>	104,453
<b>NET CURRENT ASSETS</b>		<b>6,087,809</b>	3,987,780
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>7,068,229</b>	4,433,257
<b>NON-CURRENT LIABILITIES</b>			
Convertible loan		<b>1,200,564</b>	1,149,550
Lease liabilities		<b>47,442</b>	17,165
Long term payables		<b>37,693</b>	–
Deferred income		<b>123,611</b>	100,000
Deferred tax liabilities		<b>–</b>	6,036
Total non-current liabilities		<b>1,409,310</b>	1,272,751
Net assets		<b>5,658,919</b>	3,160,506
<b>EQUITY</b>			
<b>Equity attributable to owners of the parent</b>			
Share capital		<b>19</b>	16
Reserves		<b>5,604,540</b>	3,103,996
Non-controlling interests		<b>5,604,559</b>	3,104,012
		<b>54,360</b>	56,494
Total equity		<b>5,658,919</b>	3,160,506

## 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. During the year, the Company's subsidiaries were involved in the research and development of biological products. Orelabrutinib, a drug developed by the company, was sold commercially in China in January 2021, and other pipelines are at different pre-clinical and clinical research and development stages respectively. The shares of the Company were listed on the Main Board of the Stock Exchange of Hong Kong Limited. (the "Hong Kong Stock Exchange") on 23 March 2020.

#### 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%	Clinical trial
InnoCare Pharma Australia Pty Ltd.	Australia	AU\$10	–	100%	Clinical trial
Beijing InnoCare Pharma Tech Co., Ltd. ("Beijing InnoCare") <sup>(a)</sup>	PRC/Mainland China	US\$80,000,000	–	100%	Research and development
Nanjing Tian Yin 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 Tian Jin 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%	Biologics manufacturing
Guangzhou InnoCare Biological Tech Co., Ltd. <sup>(a)</sup>	PRC/Mainland China	US\$30,000,000	–	100%	Research and development

(a) Registered as a wholly-foreign-owned enterprise 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 derivative financial instruments and wealth management products 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 2021. 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).

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 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16	<i>Interest Rate Benchmark Reform – Phase 2</i>
Amendment to HKFRS 16	<i>Covid-19-Related Rent Concessions</i>
Amendment to HKFRS 16	<i>Covid-19-Related Rent Concessions beyond 30 June 2021 (early adopted)</i>

The nature and the impact of the revised HKFRSs are described below:

- (a) Amendments to HKFRS 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16 address issues not dealt with in the previous amendments which affect financial reporting when an existing interest rate benchmark is replaced with an alternative risk-free rate (“RFR”). The amendments provide a practical expedient to allow the effective interest rate to be updated without adjusting the carrying amount of financial assets and liabilities when accounting for changes in the basis for determining the contractual cash flows of financial assets and liabilities, if the change is a direct consequence of the interest rate benchmark reform and the new basis for determining the contractual cash flows is economically equivalent to the previous basis immediately preceding the change. In addition, the amendments permit changes required by the interest rate benchmark reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued. Any gains or losses that could arise on transition are dealt with through the normal requirements of HKFRS 9 to measure and recognise hedge ineffectiveness. The amendments also provide a temporary relief to entities from having to meet the separately identifiable requirement when an RFR is designated as a risk component. The relief allows an entity, upon designation of the hedge, to assume that the separately identifiable requirement is met, provided the entity reasonably expects the RFR risk component to become separately identifiable within the next 24 months. Furthermore, the amendments require an entity to disclose additional information to enable users of financial statements to understand the effect of interest rate benchmark reform on an entity's financial instruments and risk management strategy. The amendments did not have any impact on the financial position and performance of the Group.
- (b) Amendment to HKFRS 16 issued in April 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the covid-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The amendment is effective retrospectively for annual periods beginning on or after 1 April 2021 with any cumulative effect of initially applying the amendment recognised as an adjustment to the opening balance of retained profits at the beginning of the current accounting period. Earlier application is permitted.

The Group has early adopted the amendment on 1 January 2021. However, the Group has not received covid-19-related rent concessions and plans to apply the practical expedient when it becomes applicable within the allowed period of application.

## 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 3	<i>Reference to the Conceptual Framework<sup>1</sup></i>
Amendments to HKFRS 10 and HKAS 28 (2011)	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture<sup>3</sup></i>
HKFRS 17	<i>Insurance Contracts<sup>2</sup></i>
Amendments to HKFRS 17	<i>Insurance Contracts<sup>2,5</sup></i>
Amendments to HKFRS 17	<i>Initial Application of HKFRS 17 and HKFRS 9-Comparative Information<sup>2</sup></i>
Amendments to HKAS 1	<i>Classification of Liabilities as Current or Non-current<sup>2,4</sup></i>
Amendments to HKAS 1 and HKFRS Practice Statement 2	<i>Disclosure of Accounting Policies<sup>2</sup></i>
Amendments to HKAS 8	<i>Definition of Accounting Estimates<sup>2</sup></i>
Amendments to HKAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction<sup>2</sup></i>
Amendments to HKAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use<sup>1</sup></i>
Amendments to HKAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract<sup>1</sup></i>
<i>Annual Improvements to HKFRSs 2018-2020</i>	Amendments to HKFRS 1, HKFRS 9, Illustrative Examples accompanying HKFRS 16, and HKAS 41 <sup>1</sup>

<sup>1</sup> Effective for annual periods beginning on or after 1 January 2022

<sup>2</sup> Effective for annual periods beginning on or after 1 January 2023

<sup>3</sup> No mandatory effective date yet determined but available for adoption

<sup>4</sup> As a consequence of the amendments to HKAS 1, 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 in October 2020 to align the corresponding wording with no change in conclusion

<sup>5</sup> 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

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

Amendments to HKFRS 3 are intended to 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* 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 expects to adopt the amendments prospectively from 1 January 2022. Since the amendments apply prospectively to business combinations for which the acquisition date is on or after the date of first application, the Group will not be affected by these amendments on the date of transition.

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 HKAS 1 *Classification of Liabilities as Current or Non-current* clarify the requirements for classifying liabilities as current or non-current. The amendments specify that if an entity's right to defer settlement of a liability is subject to the entity complying with specified conditions, the entity has a right to defer settlement of the liability at the end of the reporting period if it complies with those conditions at that date. 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. The amendments are effective for annual periods beginning on or after 1 January 2023 and shall be applied retrospectively. Earlier application is permitted. 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 assessing the impact of the amendments on the Group's accounting policy disclosures.

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 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 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 a deferred tax asset and a deferred tax liability for deductible and taxable temporary differences associated with right-of-use assets and lease liabilities, and recognise the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained profits at the beginning of the earliest comparative period presented.

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, in profit or loss. The amendments are effective for annual periods beginning on or after 1 January 2022 and shall be applied retrospectively only to items of property, plant and equipment made available for use on or after the beginning of the earliest period presented in the financial statements in which the entity first applies the amendments. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

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 amendments are effective for annual periods beginning on or after 1 January 2022 and shall be applied to contracts for which an entity has not yet fulfilled all its obligations at the beginning of the annual reporting period in which it first applies the amendments. Earlier application is permitted. Any cumulative effect of initially applying the amendments shall be recognised as an adjustment to the opening equity at the date of initial application without restating the comparative information. The amendments are not expected to have any significant impact on the Group's financial statements.

*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 expected to be 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. An entity applies the amendment to financial liabilities that are modified or exchanged on or after the beginning of the annual reporting period in which the entity first applies the amendment. The amendment is effective for annual periods beginning on or after 1 January 2022. Earlier application is permitted. The amendment is not expected to have a significant impact on the Group's financial statements.
- *HKFRS 16 Leases*: removes the illustration of payments from the lessor relating to leasehold improvements in Illustrative Example 13 accompanying HKFRS 16. This removes potential confusion regarding the treatment of lease incentives when applying HKFRS 16.

### 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 China, and most of the Group's identifiable operating assets and liabilities are located in China, the Group only has one reportable operating segment.

#### Geographical information

##### (a) Revenue from external customers

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
– Mainland China	216,066	1,364
– Overseas	826,967	–
	<u>1,043,033</u>	<u>1,364</u>

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

##### (b) Non-current assets

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
– Mainland China	672,641	444,142
– Overseas	1,016	1,335
	<u>673,657</u>	<u>445,477</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 which accounted for 10% or more of the Group's revenue during the year is set out below:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Customer A	826,967	–
Customer B	–	427
Customer C	–	133
	<u>826,967</u>	<u>560</u>

#### 4. PRIOR YEAR ADJUSTMENT

The management has identified the following errors in the previously issued consolidated financial statements.

The convertible redeemable preferred shares were automatically converted into ordinary shares on 23 March 2020. As a result, the ending balance of the convertible redeemable preferred shares as of 23 March 2020 were reclassified into share capital and share premium of the Company. The Company's reporting currency is different from its functional currency, and the differences between the balance of convertible redeemable preferred shares as of 31 December 2019 and 23 March 2020 should include both the fair value changes of convertible redeemable preferred shares and exchange differences on translation of foreign operations during the period in between. Due to a human error, the total differences, including the exchange difference on translation of foreign operations of RMB72,398,000, were incorrectly recorded in fair value changes of convertible redeemable preferred shares, resulting in an overstatement of fair value changes of convertible redeemable preferred shares of RMB72,398,000 and understatement of the exchange differences on translation of foreign operations of the same amount.

Consequently, the consolidated statements of profit or loss, comprehensive income, changes in equity and cash flows for the year ended 31 December 2020 and certain explanatory notes have been restated to reflect these corrections. There were reclassifications between accumulated losses and foreign exchange reserve with no impact to the consolidated statements of financial position as of 31 December 2020, as they form an integral part of the reserves in the consolidated statement of financial position of the Group.

For details of the said errors, please refer to the clarification announcement of the Company dated 27 August 2021, published on the website of the Stock Exchange.

Impact to the consolidated statement of profit or loss and consolidated statement of comprehensive income for the year ended 31 December 2020 is set out below:

	<b>The Group as previously reported</b> <i>RMB'000</i>	<b>Prior year adjustment</b> <i>RMB'000</i>	<b>The Group as restated</b> <i>RMB'000</i>
Fair value changes of convertible redeemable preferred shares	(141,579)	72,398	(69,181)
Exchange differences on translation of foreign operations	(251,702)	(72,398)	(324,100)
Loss for the year	(464,263)	72,398	(391,865)
Loss for the year attributable to owners of the parent	(463,793)	72,398	(391,395)
Loss per share attributable to ordinary equity holders of the parent – Basic and diluted	(RMB0.48)	RMB0.08	(RMB0.40)

Impact to the consolidated statement of cash flows for the year ended 31 December 2020 is set out below:

	<b>The Group as previously reported</b> <i>RMB'000</i>	<b>Prior year adjustment</b> <i>RMB'000</i>	<b>The Group as restated</b> <i>RMB'000</i>
Loss before tax	(464,263)	72,398	(391,865)
Fair value changes of convertible redeemable preferred shares	(141,579)	72,398	(69,181)

## 5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Revenue from contracts with customers	<u><u>1,043,033</u></u>	<u><u>1,364</u></u>

### (a) Disaggregated revenue information

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Revenue from contracts with customers		
– License out	775,963	–
– Sales of goods	214,666	–
– Research and development services	51,003	–
– Other services	<u>1,401</u>	<u>1,364</u>
	<u><u>1,043,033</u></u>	<u><u>1,364</u></u>
Geographical markets		
– Mainland China	216,066	1,364
– Overseas	<u>826,967</u>	<u>–</u>
	<u><u>1,043,033</u></u>	<u><u>1,364</u></u>
Timing of revenue recognition from contracts with customers		
– At a point in time	992,030	–
– Over time	<u>51,003</u>	<u>1,364</u>
	<u><u>1,043,033</u></u>	<u><u>1,364</u></u>

The transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December 2020 are as follows:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Within one year	<u><u>6,831</u></u>	<u><u>–</u></u>

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

	<b>2021</b>	2020
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
<u>Other income</u>		
Government grants (note)	<b>16,257</b>	64,439
Bank interest income	<b>135,135</b>	96,809
Compensation income	<b>2,608</b>	–
Investment income from investments in wealth management products	<b>70</b>	1,766
	<b>154,070</b>	163,014
<u>Gains</u>		
Fair value changes of financial assets at fair value through profit or loss	<b>6,733</b>	–
Foreign exchange gains, net	<b>57,135</b>	108,290
	<b>217,938</b>	271,304

Note: Government grants have been received from the PRC local government authorities to support the subsidiaries' research and development activities and the purchase of certain items of property, plant and equipment.

## 6. 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% (2020: 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 (2020: HK\$2,000,000) of assessable profits of this subsidiary are taxed at 8.25% (2020: 8.25%) and the remaining assessable profits are taxed at 16.5% (2020: 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 was recognised as High and New Technology Enterprise and are entitled to a preferential tax rate of 15% (2020: 15%). Nanjing InnoCare was recognised as High and New Technology Enterprise and its status is up for renewal in 2021 which is in progress (2020: 15%).

## Australia

The subsidiary incorporated in Australia is subject to income tax at the rate of 27.5% (2020: 27.5%) on the estimated assessable profits arising in Australia during the year.

## United States of America

The subsidiary incorporated in Delaware, United States is subject to statutory United States federal corporate income tax at a rate of 21% (2020: 21%). It is also subject to the state income tax in Delaware at a rate of 8.7% (2020: 8.7%) during the year.

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Income tax expense		
Current income tax expense	52,593	–
Deferred income tax expense	(6,035)	–
	<u>46,558</u>	<u>–</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:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i> (Restated)
Loss before tax	<u>(20,121)</u>	<u>(391,865)</u>
Tax at the statutory tax rate of 25%	(5,030)	(97,966)
Effect of tax rate differences in other jurisdictions	22,370	38,720
Preferential tax rates applicable to certain subsidiaries	(23,565)	24,972
Additional deductible allowance for qualified research and development costs	(56,802)	(27,348)
Income not subject to tax	(82,003)	–
Tax losses not recognised	134,184	60,517
Expenses not deductible for tax	4,720	1,105
Losses attributable to joint ventures	91	–
Withholding tax from license and collaboration revenue	52,593	–
Tax charge at the Group's effective rate	<u>46,558</u>	<u>–</u>

The Group has tax losses arising in Mainland China of RMB1,177,329,000 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.

## 7. DIVIDEND

No dividends have been declared and paid by the Company for the year ended 31 December 2021 (2020: Nil).

## 8. 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:

	<b>Year ended December 31</b>	
	<b>2021</b> <i>RMB'000</i>	<b>2020</b> <i>RMB'000</i>
<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><u>(66,679)</u></u>	<u><u>(391,865)</u></u>
	<b>2021</b>	<b>2020</b>
	<b>Number of shares</b> <i>'000</i>	<b>Number of shares</b> <i>'000</i>
<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><u>1,366,261</u></u>	<u><u>967,576</u></u>

The computation of basic and diluted loss per share for the years ended 31 December 2021 and 2020 excluded the unvested share options and 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 2021 and 2020 in respect of a dilution as the impact of the conversion of the convertible redeemable preferred shares, the exercise of share options and restricted stock units, or the convertible loan 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 2021 and 2020 are the same as the basic loss per share amounts.

## 9. TRADE RECEIVABLES

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Trade receivables	45,304	152
Impairment	<u>(31)</u>	<u>–</u>
Trade receivables	<u><u>45,273</u></u>	<u><u>152</u></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 and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. In view of the fact that the Group's trade receivables are immaterial and 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, is as follows:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Within 3 months	<u><u>45,273</u></u>	<u><u>152</u></u>

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

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
At beginning of year	–	–
Impairment losses	32	–
Amount written off as uncollectible	<u>(1)</u>	<u>–</u>
At end of year	<u><u>31</u></u>	<u><u>–</u></u>

An impairment analysis is performed at each reporting date using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns by product type and rating. 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:

	<b>Gross carrying Amount</b> <i>RMB'000</i>	<b>Expected loss rate</b>	<b>Expected credit loss</b> <i>RMB'000</i>
Trade receivables aged Less than 1 year	<u>45,304</u>	<u>0.07%</u>	<u>31</u>

## 10. 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:

	<b>2021</b> <i>RMB'000</i>	2020 <i>RMB'000</i>
Within 3 months	<b>81,697</b>	3,987
3 to 6 months	<b>1,505</b>	382
6 to 12 months	<b>1,257</b>	1,086
Over 12 months	<u><b>143</b></u>	<u>65</u>
	<u><b>84,602</b></u>	<u>5,520</u>

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

## 11. EVENTS AFTER THE REPORTING PERIOD

On 16 March 2022, the Group granted 1,820,000 RSUs which shall be vested at an exercise price of US\$0.178 to certain eligible individuals under the 2018 Global Share Plan.

## 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](http://www.hkexnews.hk) and the website of the Company at [www.innocarepharma.com](http://www.innocarepharma.com). The annual report of the Group for the year ended 31 December 2021 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 2022.

## 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.

“2016 Pre-IPO Incentivisation Plan”	the pre-IPO employee global share plan adopted by the Company on 6 September 2016 and as amended by the resolutions in writing by the Board passed on 5 February 2018
“2018 Pre-IPO Incentivisation Plan”	the pre-IPO employee global share plan adopted by the Company on 28 November 2018
“AD”	Atopic Dermatitis
“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
“Ba/F3”	a murine interleukin-3 dependent pro-B cell line is increasingly popular as a model system for assessing both the potency and downstream signaling of kinase oncogenes, and the ability of small-molecule kinase inhibitors to block kinase activity
“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
“BCR”	B-cell receptor
“Biogen”	Biogen Inc. (Nasdaq: BIIB)
“Board”	the board of directors of the company
“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 and Corporate Governance Report 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
“CMO”	contract manufacture organization
“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 November 3, 2015, the shares of which are listed on the Main Board of the Hong Kong Stock Exchange
“Compensation Committee”	the compensation committee of the Board
“CYP3A4”	Cytochrome P450 3A4, is an important enzyme in the body, mainly found in the liver and in the intestine
“CYP450s”	Cytochromes P450, are a superfamily of enzymes containing heme as a cofactor that function as monooxygenases
“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
“FGFR”	B-lymphocyte antigen CD20, a B-cell specific cell surface molecule that is encoded by the MS4A1 gene
“FL”	Follicular Lymphoma
“GCB”	germinal center B-cell, one of the subtypes of diffuse large B-cell lymphoma
“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
“HCC”	hepatocellular carcinoma, a type of cancer arising from hepatocytes in predominantly cirrhotic liver
“hERG”	a gene that codes for a protein known as Kv11.1, the alpha subunit of a potassium ion channel
“Hillhouse”	Hillhouse Capital Advisors, Ltd., sole investment manager of Gaoling Fund L.P. and YHG Investments L.P.
“HK\$” or “HKD”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“Hong Kong Stock Exchange” or “Stock Exchange”	The Stock Exchange of Hong Kong Limited
“IBD”	inflammatory bowel disease
“ICP-022” or “Orelabrutinib”	one of the Company’s commercialized products with multiple registrational ongoing trials and several clinical trials in both hema-oncology and autoimmune therapeutics
“ICP-105”	one of the Company’s clinical stage drug candidates
“ICP-192”	one of the Company’s clinical stage drug candidates
“IL-2”	Interleukin-2
“IL-5”	Interleukin-5
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or clinical trial notification in Australia
“InnoCare Nanjing”	Nanjing Tian Yin Jian Hua Pharm Tech Co., Ltd.
“IPO”	the initial public offering of the Company on the Hong Kong Stock Exchange
“IRC”	Independent Review Board
“ITK”	inducible T cell kinase
“ITP”	Immune Thrombocytopenia
“iwNHL”	International Working Group Criteria for Non-Hodgkin Lymphoma
“JAK”	Janus tyrosine kinase

“Keymed”	Keymed Biosciences Inc. (“2162.HK”)
“KM12”	one of the cell lines of the NCI-60 panel which represents different cancer types and has been widely utilized for drug screening and molecular target identification. KM12 is colorectal cancer cell line carrying TPM3-NTRK1 gene fusion
“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 Main Board of the Hong Kong Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited
“LMNA”	also known as Lamin A/C, is a protein that in humans is encoded by the LMNA gene. Lamin A/C belongs to the lamin family of proteins
“LN”	Lupus Nephritis
“LVC Entities”	Loyal Valley Capital Advantage Fund LP, Loyal Valley Capital Advantage Fund II LP and LVC Lion Fund LP
“MCL”	mantle cell lymphoma, a type of B-cell non-Hodgkin lymphoma
“MCD”	a subtype of diffuse large B-cell lymphoma (DLBCLs), based on co-occurrence of MYD88L265P and CD79B mutations (MCD subtype)
“Mebworks”	Beijing Mebworks Biotech Company Limited
“MM”	multiple myeloma
“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 optica 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總局)
“Nomination Committee”	the nomination committee of the Board
“NRDL”	National drug reimbursement list



“NTRK”	neurotrophic tyrosine receptor kinase
“OBD”	optimal biological dose, dose associated with a prespecified desired effect on a biomarker
“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
“Pre-IPO Incentivisation Plans”	the 2015 Pre-IPO Incentivisation Plan, the 2016 Pre-IPO Incentivisation Plan and the 2018 Pre-IPO Incentivisation Plan
“Prospectus”	the prospectus of the Company, dated March 11, 2020, in relation of its Global Offering
“R&D”	research and development
“RA”	Rheumatoid Arthritis
“R/R” or “r/r”	relapsed and refractory
“Reporting Period”	year ended 31 December 2021
“RMB”	Renminbi, the lawful currency of the PRC
“RSU(s)”	restricted share unit(s)
“RP2D”	recommended phase 2 dose
“R-CHOP”	a combination of five drugs as first-line treatment for aggressive non-Hodgkin’s lymphoma
“RRMM”	relapsing-resetting multiple sclerosis
“SD rats”	Sprague Dawley rat, is an outbred multipurpose breed of albino rat used extensively in medical and nutritional research
“Share(s)”	ordinary shares with a par value of US\$0.000002 per share in the share capital of the Company
“SHP2”	a 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
“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
“TEAEs”	treatment-emergent adverse events
“TRK”	a family of tyrosine kinases that regulates synaptic strength and plasticity in the mammalian nervous system
“TRKA G595R”	TRKA kinase with a mutation of G595R, i.e. changes of amino acid at 595 from glycine (G) to arginine (R)
“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”	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, China, 23 March 2022

*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. Quanhong Yuan, Mr. Shan Fu and Mr. Ronggang Xie as non-executive Directors, and Dr. Zemin Zhang, Ms. Lan Hu and Dr. Kaixian Chen as independent non-executive Directors.*