Abbisko Cayman Limited
和譽開曼有限責任公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2256)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022

The board of directors (the "**Board**") of Abbisko Cayman Limited (the "**Company**") is pleased to announce the consolidated annual results of the Company and its subsidiaries (the "**Group**", "**we**", "**our**" or "**us**") for the year ended December 31, 2022 (the "**Reporting Period**"), together with comparative figures for the year ended December 31, 2021.

BUSINESS HIGHLIGHTS

We have made significant progresses in many aspects in 2022 and as of March 15, 2023.

Further advanced our clinical-stage assets

Pimicotinib (ABSK021)

- We are conducting a Phase Ib trial for pimicotinib in the U.S. and mainland China concurrently. We have completed patient enrollment for the tenosynovial giant cell tumor ("**TGCT**") cohorts at 50mg QD and 25mg QD of the Phase Ib trial in mainland China.

- In July 2022, pimicotinib was granted the breakthrough therapy designation ("**BTD**") by National Medical Products Administration of the People's Republic of China ("**NMPA**") for the treatment of TGCT that is not amenable to surgery. This BTD approval was based on preliminary trial results from the TGCT cohort of the ongoing Phase Ib clinical trial in China for pimicotinib.

- In October 2022, pimicotinib was approved by NMPA for a randomized, double-blind, placebo-controlled and multicenter Phase III clinical study in patients with TGCT. Pimicotinib is the first highly selective CSF-1R inhibitor developed by a Chinese company that has entered Phase III clinical trial.

- In November 2022, the preliminary Phase Ib results of pimicotinib for advanced TGCT were published at the 2022 Connective Tissue Oncology Society annual meeting. The data demonstrated excellent antitumor efficacy and the safety profile of pimicotinib in the treatment of patients with advanced TGCT. Pimicotinib demonstrated significant antitumor efficacy with a preliminary objective response rate ("**ORR**") of 68.0% (17/25, 95% CI: 46.50%-85.05%), including one complete response and 16 partial responses confirmed by independent review committee ("**IRC**") within six months. The safety profile of pimicotinib was favorable with no apparent hepatotoxicity. The mean treatment duration was 6.8 months, and 85.2% of patients are still on treatment.

- In January 2023, pimicotinib was approved by the NMPA for a Phase II clinical study in patients with chronic graft-versus-host disease ("**cGvHD**"). Pre-clinical data indicated that pimicotinib is a highly potent and selective small molecule inhibitor of CSF-1R that may play important roles for treating many human diseases including complications associated with transplantation.

- In January 2023, pimicotinib was granted the BTD from the U.S. Food and Drug Administration ("**U.S. FDA**") for the treatment of TGCT patients that are not amenable to surgery. This BTD approval was based on results from the Phase Ib clinical trial of TGCT cohort for pimicotinib.

Irpagratinib (ABSK011)

- We are conducting a Phase Ib monotherapy trial in second-line treatment of hepatocellular carcinoma ("**HCC**") patients with FGF19 overexpression in mainland China and have completed patient enrollment of the 180mg QD cohort. We are further exploring higher doses and different dose regimen in Phase Ia and have started patient enrollment of 160mg BID cohort and 320mg QD cohort.

- We are also conducting a Phase II trial of irpagratinib in combination with the anti-PD-L1 antibody atezolizumab from F. Hoffmann-La Roche Ltd. and Roche China Holding Ltd. ("**Roche**") in late stage HCC patients with FGF19 overexpression in mainland China. The first patient was dosed in January 2022. Patient enrollment is ongoing.

- In December 2022, we reported the preliminary Phase I efficacy and safety results of irpagratinib in the treatment of second-line HCC with FGF19 overexpression.

- The preliminary proof-of-concept data of irpagratinib Phase I has shown promising efficacy in FGF19+ HCC patients, with 22% ORR (4/18) in patients with high FGF19 expression and 33.3% ORR (2/6) in the 160mg BID FGF19 IHC+ cohort. Irpagratinib was well tolerated across all cohorts.

Fexagratinib (ABSK091, AZD4547)

- We are conducting a Phase II trial in mainland China for fexagratinib in patients with locally advanced or metastatic urothelial carcinoma with FGFR2/3 genetic alterations. We dosed the first patient in November 2021 and patient enrollment is ongoing.

- In February 2022, we entered into partnership with BeiGene, Ltd. ("**BeiGene**") for combination therapy of fexagratinib and tislelizumab, an anti-PD-1 antibody developed by BeiGene, for the treatment of urothelial cancer with FGFR2/3 genetic alterations. In May 2022, we received the Investigational New Drug (the "**IND**") approval from NMPA.

- In November 2022, we completed the first patient enrollment for this Phase II clinical trial. This is the first clinical combination trial of a pan-FGFR inhibitor with an immunotherapy in China.

- In December 2022, we announced the preliminary Phase II efficacy and safety results of fexagratinib in patients with urothelial carcinoma harboring FGFR2 or FGFR3 alterations in mainland China.

- The preliminary efficacy results showed an ORR confirmed by IRC of 30.7% (4/13) in mUC patients with FGFR3 alterations (including mutations and/or fusions) and an IRC confirmed ORR of 44% (4/9) in patients with FGFR3 mutations, which is consistent with results from the prior BISCAY trial of fexagratinib in similar patient groups outside of China. The preliminary safety results showed that 80mg BID of fexagratinib was well-tolerated in Chinese patients, and no drug related grade 4 or above adverse effects were reported. These results support further development of fexagratinib in the ongoing Phase II trial.

- In addition to urothelial carcinoma, we also plan to conduct clinical trials for fexagratinib in other solid tumors. In March 2022, we received Orphan Drug Designation ("**ODD**") granted by the U.S. FDA to fexagratinib in gastric cancer.

ABSK043

- We are conducting a Phase I trial in Australia to assess the safety, tolerability and PK/PD profile of ABSK043 in patients with solid tumors. Patient enrollment is ongoing.

- In March 2022, we received the IND approval for a Phase I trial of ABSK043 in the treatment of patients with solid tumors in mainland China. In September 2022, we completed the dosing of the first patient in China for this trial.

ABSK061

- We have received IND approvals in both mainland China and the U.S. to conduct a Phase I clinical trial for ABSK061 in patients with solid tumors. In June 2022, we dosed the first patient. Patient enrollment is ongoing.

ABSK121

- In November 2022, we obtained clinical trial approval from the U.S. FDA for ABSK121, and will launch the first Phase I clinical trial in humans for the treatment of advanced solid tumors.

ABSK081

- We are conducting a Phase Ib/II clinical trial of ABSK081 (mavorixafor) in combination with toripalimab from Shanghai Junshi Biomedical Technology Co., Ltd. ("**Junshi**") in triple-negative breast cancer ("**TNBC**") patients in mainland China. Patient enrollment has been completed.

Established a worldwide co-discovery collaboration with Eli Lilly and Company ("Lilly")

In January 2022, we entered into a worldwide co-discovery collaboration with Lilly for the discovery, development and potential commercialization of novel molecules against an undisclosed target.

- We are responsible for the discovery and development of such molecules using our proprietary research and development ("**R&D**") platform.

- Lilly has joined the effort by providing prior discovery information associated with this target as well as certain additional disease knowledge and expertise.

- Lilly will have the right to further develop and commercialize the compounds if the compounds meet the agreed endpoints.

- We are eligible to receive up to US$258 million in potential payments upon achievement of pre-specified preclinical, clinical development and commercial milestones, as well as tiered royalties on sales, if Lilly is responsible for further clinical development and commercialization.

Reached an exclusive out-license agreement with Shanghai Allist Pharmaceuticals Co., Ltd. ("Allist")

In March 2023, we entered into an exclusive out-license agreement with Allist.

- We granted Allist the research, development, manufacture, use, and sales of ABK3376 (a next-generation EGFR-TKI) in Greater China Region (Mainland China, Hong Kong, Macau, and Taiwan).

- We also granted Allist a time-limited option to expand the licensed territory to worldwide in accordance with the terms and conditions agreed upon by both parties.

- We will receive upfront, development, and sales milestone payments up to US$187.90 million in total, plus tiered royalty payments based on the net sales.

Continued to move forward pre-clinical candidates

Despite the lockdown in Shanghai due to COVID-19 in the first half of 2022, we have taken various measures to minimize the impact on our pre-clinical programs and advanced the following three programs into late IND-enabling stage:

- **ABSK051** – a small molecule CD73 inhibitor which could be applied for the treatment of various tumor types including lung cancer, pancreatic cancer and other cancers;

- **ABSK012** – a next-generation small molecule FGFR4 inhibitor with strong potency against both wild-type and mutant FGFR4; and

- **ABSK112** – A next-generation EGFR-exon20 inhibitor with improved selectivity over wild-type EGFR and strong brain-penetrating ability.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards ("IFRS") Measures:

Cash and bank balances. Cash and bank balances as at December 31, 2022 were RMB2,258.8 million (approximately US$324.3 million), an decrease by RMB286.7 million from RMB2,545.5 million for the year ended December 31, 2021, primarily attributable to continuous expansion and rapid progress of various R&D pipelines, partially offset by impact from foreign exchange volatility.

Revenue. Revenue for the year ended December 31, 2022 was zero, while revenue for the year ended December 31, 2021 was RMB22.7 million which was attributed to an out-license upfront payment generated from one of our clinical candidates.

Other income and gains. Other income and gains increased by RMB2.0 million from RMB43.6 million for the year ended December 31, 2021 to RMB45.6 million for the year end December 31, 2022, primarily attributable to the increase in bank interest income.

Research and development expenses. Our R&D expenses primarily consisted of expenses in connection with exploratory research, pre-clinical research and clinical research, as well as reagent costs, employee costs, share-based payments and depreciation. R&D expenses increased by RMB152.6 million from RMB226.1 million for the year ended December 31, 2021 to RMB378.7 million for the year ended December 31, 2022, primarily attributable to advancement of our pipeline programs and continuous expansion of functions related to R&D.

Administrative expenses. Administrative expenses decreased by RMB6.4 million from RMB124.8 million for the year ended December 31, 2021 to RMB118.4 million for the year ended December 31, 2022, primarily attributable to the absence of IPO related expenses, while partially offset by continuous expansion of workforce in non-R&D related function and increased professional service fees.

Finance costs. Finance costs increased by RMB1.7 million from RMB1.0 million for the year ended December 31, 2021 to RMB2.7 million for the year ended December 31, 2022, mainly due to the increase of interest on lease liabilities.

Fair value losses on convertible redeemable preferred shares. Fair value losses on convertible redeemable preferred shares decreased by RMB1,524.3 million from RMB1,524.3 million for the year ended December 31, 2021 to zero for the year ended December 31, 2022. The convertible redeemable preferred shares had been converted into ordinary shares upon the listing of the Company's shares, and will not affect our financial performance in the subsequent financial years.

Loss for the year. Loss for the year decreased by RMB1,314.4 million from RMB1,810.0 million for the year ended December 31, 2021 to RMB495.6 million for the year ended December 31, 2022, primarily attributable to the combination of impacts from 1) elimination of fair value losses on convertible redeemable preferred shares; 2) increase in R&D expenses; and 3) decrease in revenue.

Non-International Financial Reporting Standards ("Non-IFRS") Measures:

Research and development expenses excluding share-based compensation cost increased by RMB137.3 million from RMB176.3 million for the year ended December 31, 2021 to RMB313.6 million for the year ended December 31, 2022, primarily attributable to advancement of our pipeline programs, as well as the continuous expansion of functions related to R&D.

Administrative expenses excluding share-based compensation cost decreased by RMB11.3 million from RMB84.7 million for the year ended December 31, 2021 to RMB73.4 million for the year ended December 31, 2022, primarily attributable to the absence of IPO related expenses, while partially offset by the expansion of workforce in non-R&D related functions.

Loss for the year excluding the effect of the fair value losses on convertible redeemable preferred shares and share-based compensation cost increased by RMB189.8 million from RMB195.7 million for the year ended December 31, 2021 to RMB385.5 million for the year ended December 31, 2022, primarily attributable to: 1) an increase in R&D expenses; 2) a decrease in revenue; and 3) an increase in other expenses resulted from fluctuation of foreign exchange differences.

I. FINANCIAL INFORMATION

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	Notes	**2022** ***RMB'000***	2021 *RMB'000*
Revenue	4	**–**	22,682
Cost of sales		**–**	–
Gross profit		**–**	22,682
Other income and gains	5	**45,563**	43,587
R&D expenses		**(378,746)**	(226,126)
Administrative expenses		**(118,443)**	(124,777)
Other expenses		**(41,295)**	(80)
Fair value losses on convertible redeemable preferred shares		**–**	(1,524,320)
Finance costs	7	**(2,685)**	(959)
LOSS BEFORE TAX	6	**(495,606)**	(1,809,993)
Income tax expenses	8	**–**	–
LOSS FOR THE YEAR		**(495,606)**	(1,809,993)
OTHER COMPREHENSIVE INCOME			
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		**774**	53,268
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of the Company		**199,493**	(60,895)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX		**200,267**	(7,627)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		**(295,339)**	(1,817,620)
Loss attributable to:			
Owners of the parent		**(495,606)**	(1,809,993)
Total comprehensive loss attributable to:			
Owners of the parent		**(295,339)**	(1,817,620)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	10		
Basic and diluted			
For loss for the year		**RMB0.80**	RMB7.71

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	**2022**	2021
		RMB'000	*RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**32,364**	15,209
Right-of-use assets		**44,936**	54,085
Intangible assets		**4,505**	3,051
Other non-current assets		**27**	805
Total non-current assets		**81,832**	73,150
CURRENT ASSETS			
Prepayments and other receivables	12	**55,094**	35,876
Financial assets at fair value through profit or loss	11	**93,796**	–
Cash and bank balances	13	**2,258,827**	2,545,513
Total current assets		**2,407,717**	2,581,389
CURRENT LIABILITIES			
Other payables and accruals	14	**97,585**	64,676
Lease liabilities		**9,968**	8,862
Total current liabilities		**107,553**	73,538
NET CURRENT ASSETS		**2,300,164**	2,507,851
TOTAL ASSETS LESS CURRENT LIABILITIES		**2,381,996**	2,581,001
NON-CURRENT LIABILITIES			
Lease liabilities		**35,607**	44,942
Total non-current liabilities		**35,607**	44,942
Net assets		**2,346,389**	2,536,059
EQUITY			
Equity attributable to owners of the parent			
Share capital		**46**	46
Treasury shares		**(3)**	(5)
Other reserves		**2,346,346**	2,536,018
Total equity		**2,346,389**	2,536,059

NOTES

1.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards ("**IFRSs**") (which include all International Financial Reporting Standards, International Accounting Standards ("**IASs**") and Interpretations) issued by the International Accounting Standards Board (the "**IASB**"), and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for certain financial instruments which have been measured at fair value. These financial statements are presented in Renminbi ("**RMB**") and all values are rounded to the nearest thousand ("**RMB'000**") except when otherwise indicated.

1.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

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

Amendments to IFRS 3	*Reference to the Conceptual Framework*
Amendments to IAS 16	*Property, Plant and Equipment: Proceeds before Intended Use*
Amendments to IAS 37	*Onerous Contracts – Cost of Fulfilling a Contract*
Annual Improvements to IFRS Standards 2018-2020	*Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41*

1.3 ISSUED BUT NOT YET EFFECTIVE IFRSs

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

Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[3]
Amendments to IFRS 16	*Lease Liability in a Sale and Leaseback*[2]
IFRS 17	*Insurance Contracts*[1]
Amendments to IFRS 17	*Insurance Contracts*[1, 5]
Amendment to IFRS 17	*Initial Application of IFRS 17 and IFRS 9 – Comparative Information*[6]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current (the "2020 Amendments")*[2,4]
Amendments to IAS 1	*Non-current Liabilities with Covenants (the "2022 Amendments")*[2]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[1]
Amendments to IAS 8	*Definition of Accounting Estimates*[1]
Amendments to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*[1]

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

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

3 No mandatory effective date yet determined but available for adoption

4 As a consequence of 2022 Amendments, the effective date of the 2020 Amendments was deferred to annual periods beginning on or after January 1, 2024

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

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

2. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group's accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the financial statements:

Research and development expenses

Development expenses incurred on the Group's drug product pipelines are capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group's intention to complete and the Group's ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development expenses which do not meet these criteria are expensed when incurred. Determining the amounts to be capitalised requires management to make assumptions regarding the expected future cash generation of the assets, discount rates to be applied and the expected period of benefits. During the reporting period, all expenses incurred for R&D activities were expensed when incurred.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty as at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Share-based payments

The Group has set up the equity share option plan for the Company's directors and the Group's employees. The fair value of the options is determined by the binomial model at the grant dates.

Estimating fair value for share-based payment transactions requires the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatizing and dividend yield and making assumptions about them.

For the fair value measurement of equity-settled transactions with employees at the grant date, the Group uses a binomial model.

Leases – Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate ("**IBR**") to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group "would have to pay", which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary's functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary's stand-alone credit rating).

3. OPERATING SEGMENT INFORMATION

Operating segment information

For management purposes, the Group has only one reportable operating segment, which is the development of innovative medicines. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

Geographical information

Since nearly all of the Group's non-current assets were located in Mainland China, no geographical information in accordance with IFRS 8 *Operating Segments* is presented.

4. REVENUE

An analysis of revenue is as follows:

	2022	2021
	RMB'000	*RMB'000*
Revenue from contracts with customers	**–**	22,682

Disaggregated revenue information

For the year ended December 31, 2021

	License fee income
	RMB'000
Type of goods or services	
License fee income	22,682
Geographical market	
Mainland China	22,682
Timing of revenue recognition	
License fee income at a point in time	22,682

5. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	2022	2021
	RMB'000	*RMB'000*
Other income		
Bank interest income	**35,018**	16,938
Other gains		
Government grants*	**10,545**	14,081
Gain on disposal of an associate	**–**	5,900
Foreign exchange gains	**–**	6,668
	10,545	26,649
	45,563	43,587

* The government grants mainly represent subsidies received from the local governments for the purpose of supporting on research and clinical trial activities, allowance for new drug development and funds for talents. There were no unfulfilled conditions or contingences relating to these grants received during the year.

6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

	2022	2021
	RMB'000	*RMB'000*
Depreciation of items of property, plant and equipment	**4,569**	4,179
Depreciation of right-of-use assets	**9,555**	7,003
Amortisation of intangible assets	**1,674**	704
R&D expenses excluding depreciation and amortisation	**366,714**	218,617
Lease payments not included in the measurement of lease liabilities	**1,351**	–
Auditor's remuneration	**2,150**	2,450
Employee benefit expense (excluding directors' and chief executive's remuneration):		
Wages and salaries	**103,328**	65,644
Pension scheme contributions (defined contribution scheme)*	**18,992**	9,841
Equity-settled share option expense	**32,469**	35,376
	154,789	110,861
Share issue expenses	**–**	29,198
Foreign exchange differences, net	**41,001**	(6,668)
Fair value losses on convertible redeemable preferred shares	**–**	1,524,320
Fair value loss on financial assets at fair value through profit or loss	**219**	
Gain on disposal of an associate	**–**	5,900

* There are no forfeited contributions that may be used by the Group as the employer to reduce the existing level of contributions.

7. FINANCE COSTS

An analysis of finance costs is as follows:

	2022	2021
	RMB'000	*RMB'000*
Interest on lease liabilities	**2,685**	959

8. 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.

Hong Kong

The subsidiary incorporated in Hong Kong are subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong during the year.

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. A subsidiary was accredited as a "High and New Technology Enterprise" ("HNTE") in October 2022 and therefore it was entitled to a preferential CIT rate of 15% from January 1, 2022 to December 31, 2024. This qualification is subject to review by the relevant tax authority in the PRC for every three years.

Australia

No provision for Australia income tax has been made as the Group had no assessable profits derived from or earned in Australia during the year. The subsidiary incorporated in Australia is subject to income tax at the rate of 25% on the estimated assessable profits arising in Australia during the year.

9. DIVIDENDS

No dividend was paid or declared by the Company during the year.

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

The calculation of the basic loss per share amount is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 620,675,952 (2021: 234,883,376, after adjusting for the effect of the Share Subdivision) in issue during the year, as adjusted to reflect the rights issue during the year.

No adjustment has been made to the basic loss per share amounts presented for the years ended December 31, 2022 and 2021 in respect of a dilution as the impact of the share options and redeemable convertible preferred shares outstanding had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted loss per share are based on:

	2022	2021
	RMB'000	*RMB'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic and diluted loss per share calculation	**(495,606)**	(1,809,993)

	Numbers of shares	
	2022	2021
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic and diluted loss per share calculation	**620,675,952**	234,883,376

11. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	2022	2021
	RMB'000	*RMB'000*
Wealth management products	**93,796**	–
	93,796	–

The above wealth management product was issued by a financial institution in Hong Kong. It was mandatorily classified as financial assets at fair value through profit or loss as their contractual cash flows are not solely payments of principal and interest.

12. PREPAYMENTS AND OTHER RECEIVABLES

	2022	2021
	RMB'000	*RMB'000*
Prepayments to suppliers	**11,249**	9,393
Amounts due from related parties	**7,741**	–
Loans to employees*	**10,058**	–
Deposits and other receivables	**26,046**	26,483
	55,094	35,876

* The loans to employees were given by the Company for the purpose of enabling the employees to exercise share options.

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As at December 31, 2022 and 2021, the loss allowance was assessed to be minimal.

13. CASH AND BANK BALANCES

	2022	2021
	RMB'000	*RMB'000*
Cash and bank balances	**2,258,827**	2,545,513
Less:		
Bank deposits with original maturity of more than three months when acquired (i)	**1,616,990**	1,481,656
Cash and cash equivalents	**641,837**	1,063,857

(i) They represent time deposits with initial terms of over three months when acquired in commercial banks with annual return rates ranging from 2.55% to 4.6% (2021: 0.54% to 2.85%). None of these deposits are either past due or impaired. None of these deposits are pledged.

	2022	2021
	RMB'000	*RMB'000*
Denominated in:		
RMB	**729,738**	718,249
USD	**1,524,612**	1,825,043
HKD	**3,219**	1,352
AUD	**1,258**	869
Cash and bank balances	**2,258,827**	2,545,513

The RMB is not freely convertible into other currencies, however, under Mainland China's Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short term time deposits are made for varying periods of between one day and three months depending on the immediate cash requirements of the Group, and earn interest at the respective short term time deposit rates. The bank balances and deposits are deposited with creditworthy banks with no recent history of default.

14. OTHER PAYABLES AND ACCRUALS

	2022	2021
	RMB'000	*RMB'000*
Payroll payable	**23,196**	22,303
Payables of construction and purchase of equipment	**1,346**	18
Other tax payables	**24,051**	1,296
Share issue expenses payables	**127**	9,306
Other payables	**48,865**	31,753
	97,585	64,676

Other payables and accruals are unsecured, non-interest-bearing and repayable on demand. The carrying amounts of financial liabilities included in other payables and accruals as at the end of each of the reporting periods approximated to their fair values due to their short-term maturities.

I. BUSINESS REVIEW

Our vision

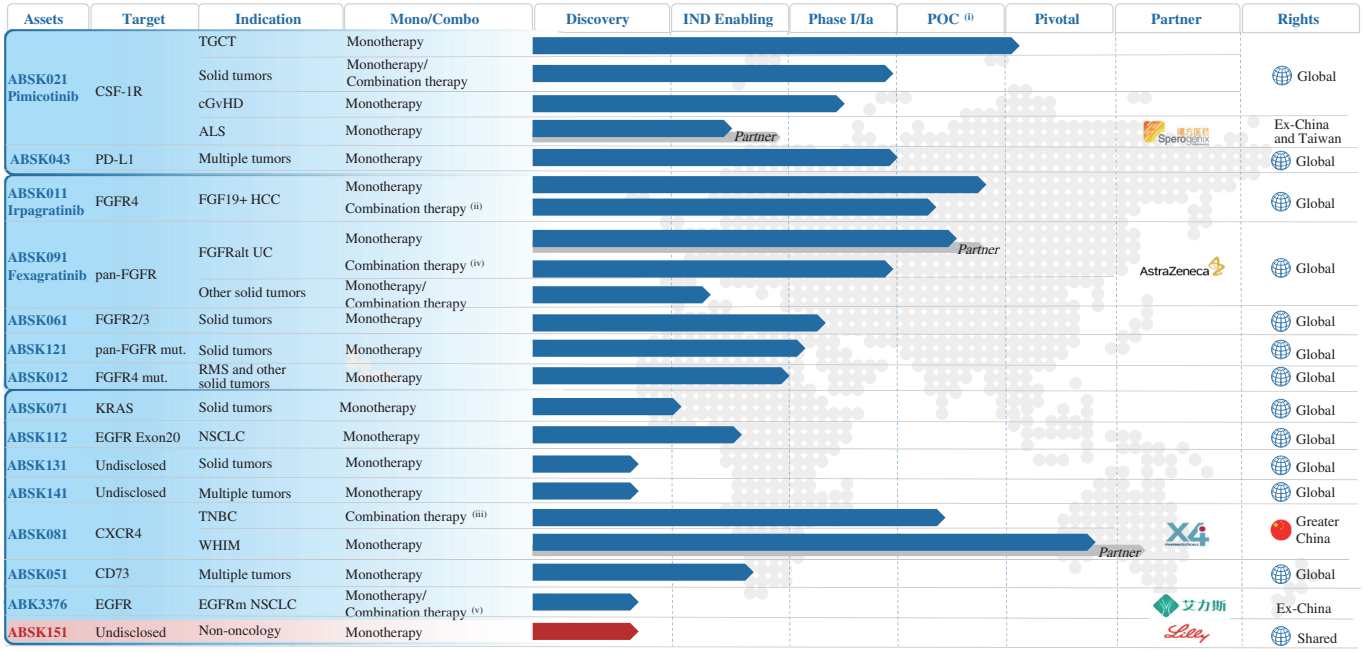
Our vision is to discover and develop novel, differentiated therapies in oncology and beyond to address critical unmet medical needs for patients in China and worldwide.

Company overview

We are a clinical-stage biopharmaceutical company primarily dedicated to the discovery and development of innovative and differentiated small molecule oncology therapies. Since our inception in 2016, we have strategically designed and developed a pipeline of 15 candidates primarily focused on oncology, including seven candidates at clinical stage. Our product candidates are primarily small molecules that focus on small molecule precision oncology and small molecule immuno-oncology therapeutic areas.

Product pipeline

We have a pipeline of 15 drug candidates ranging from pre-clinical to clinical stage programs. The following chart summarizes our pipeline and the development status of each candidate as of March 15, 2023.



Abbreviations: HCC = hepatocellular carcinoma; RMS = rhabdomyosarcoma; FGFRalt = FGFR altered; UC = urothelial cancer; GC = gastric cancer; NSCLC = non-small cell lung cancer; TGCT = tenosynovial giant cell tumor; cGvHD = chronic graft-versus-host disease; ALS = amyotrophic lateral sclerosis; TNBC = triple-negative breast cancer; WHIM = warts, hypogammaglobulinemia, infections and myelokathexis

Notes:

i. Represents Phase Ib/II clinical trial

ii. In combination with anti-PD-L1 antibody atezolizumab with Roche

iii. In combination with anti-PD-1 antibody toripalimab with Junshi

iv. In combination with anti-PD-1 antibody tislelizumab with BeiGene

v. In combination with Furmonertinib mesylate with Allist

Clinical candidates

Pimicotinib (ABSK021)

Pimicotinib is an orally bioavailable, selective, potent small molecule CSF-1R inhibitor being developed for the treatment of multiple types of oncology and non-oncology indications. The overexpression of CSF-1 is observed in many tumors and also at sites of inflammation. Indications for CSF-1R inhibitors include, the treatment of adult patients with TGCT, pancreatic cancer, colorectal cancer, cGvHD and ALS.

Current status

We are conducting a Phase Ib trial for pimicotinib in the U.S. and mainland China concurrently. We have completed patient enrollment for the TGCT cohorts at 50mg QD and 25mg QD of the Phase Ib trial in mainland China.

In July 2022, pimicotinib was granted the BTD by NMPA for the treatment of TGCT that is not amenable to surgery. This BTD approval was based on preliminary trial results from the TGCT cohort of the ongoing Phase Ib clinical trial in China for pimicotinib.

In October 2022, pimicotinib was approved by NMPA for a randomized, double-blind, placebo-controlled and multicenter Phase III clinical study in patients with TGCT. Pimicotinib is the first highly selective CSF-1R inhibitor developed by a Chinese company that has entered Phase III clinical trial.

In November 2022, the preliminary Phase Ib results of pimicotinib for advanced TGCT were published at the 2022 Connective Tissue Oncology Society annual meeting. The data demonstrated the excellent antitumor efficacy and the safety profile of pimicotinib for the treatment of patients with advanced TGCT.

Pimicotinib showed significant antitumor efficacy with a preliminary ORR of 68.0% (17/25, 95% CI: 46.50%-85.05%), including one complete response and 16 partial responses confirmed by IRC within six months. The safety profile of pimicotinib was favorable with no apparent hepatotoxicity. The mean treatment duration was 6.8 months, and 85.2% of patients are still on treatment.

Irpagratinib (ABSK011)

Irpagratinib is a potent and highly selective small molecule inhibitor of FGFR4 that we are conducting clinical trials in China. Irpagratinib is being developed for the treatment of advanced HCC with hyper-activation of FGF19/FGFR4 signaling. The FGFR4 signaling pathway is a promising direction for the development of molecularly targeted therapies in HCC. The number of patients with an overexpression of FGF19/FGFR4 account for approximately 30% of total HCC patients worldwide, according to Frost & Sullivan. Currently, no FGFR4 inhibitor has been approved to the market yet.

Current status

We are conducting a Phase Ib trial for patients in second-line HCC with FGF19 overexpression. We have completed patient enrollment for the 180mg QD cohort. Given the superior safety and quality PK/PD profiles of irpagratinib from the Phase Ia trial, we are further exploring higher doses and different dose regimen. We have started patient enrollment of 320mg QD and 160mg BID for dose escalation. We may continue to explore additional dose levels in order to identity the optimal dosage for dose expansion.

We are also conducting a Phase II trial of irpagratinib in combination with the anti-PD-L1 antibody atezolizumab from Roche in late stage HCC patients with FGF19 overexpression in mainland China. The first patient was dosed in January 2022 and patient enrollment is ongoing.

In December 2022, we announced the preliminary Phase I efficacy and safety results of irpagratinib, in the treatment of second-line HCC with FGF19 overexpression. The preliminary proof-of-concept data showed promising efficacy in FGF19+ HCC patients, with 22% ORR (4/18) in patients with high FGF19 expression and 33.3% ORR (2/6) in the 160mg BID FGF19 IHC+ cohort. Irpagratinib was well tolerated across all cohorts. Patient group with high expression of FGF19 was observed in 67% of the FGF19 IHC+ HCC patients. From safety perspective, no drug related adverse effects of grade 4 or above were reported.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK011 SUCCESSFULLY.

Fexagratinib (ABSK091, AZD4547)

Fexagratinib, previously known as AZD4547, is a highly potent and selective inhibitor of FGFR subtypes 1, 2 and 3. According to Frost & Sullivan, the cancers most commonly affected by FGFR aberration are urothelial cancer (32%), cholangiocarcinoma (25%), breast cancer (18%), endometrial carcinoma (11%) and gastric cancer (7%). Specific FGFR aberrations have been observed in a proportion of certain cancers. For example, FGFR1 amplification in squamous cell lung cancer, FGFR2 mutations in endometrial carcinoma and FGFR3 mutations in urothelial cancer.

Fexagratinib has a chemical structure different from other FGFR inhibitors with similar anti-tumor activities. Prior to the in-licensing of fexagratinib, AstraZeneca AB ("**AstraZeneca**") started conducting clinical trials on fexagratinib (AZD4547) in 2009. From 2009 to 2019, AstraZeneca sponsored and completed a total of four trials, including two Phase I trials and two Phase II trials. In November 2019, we entered into an exclusive license agreement with AstraZeneca and obtained the global rights for the development, manufacturing and commercialization of fexagratinib.

Among the clinical trials conducted by AstraZeneca, the BISCAY trial, a study in patients with advanced urothelial cancer who have progressed on prior treatments, achieved 31.3% response rate in the fexagratinib monotherapy arm, which is on par with the approved pan-FGFR inhibitor Erdafitinib in treatment of locally advanced or metastatic urothelial carcinoma with FGFR2/3 alteration (ORR 32.2%).

In another trial previously conducted by AstraZeneca in patients with previously treated advanced FGFR amplified cancer, 33% of the FGFR2-amplified gastro-oesophageal patients had confirmed responses to fexagratinib. This demonstrated that fexagratinib could potentially bring significant clinical benefits to the treatment of gastric cancer patients with FGFR alterations.

Current status

We are conducting a Phase II trial in mainland China for fexagratinib in patients with locally advanced or metastatic urothelial carcinoma with FGFR2/3 genetic alterations. We dosed the first patient in November 2021. Patient enrollment is ongoing.

In February 2022, we entered into partnership with BeiGene for combination therapy of fexagratinib and tislelizumab, an anti-PD-1 antibody developed by BeiGene for the treatment of urothelial cancer with FGFR2/3 genetic alterations. In May 2022, we received the IND approval from NMPA to initiate a Phase II trial for the combination therapy.

In November 2022, we completed the first patient enrollment for this Phase II clinical trial. This is the first clinical combination trial of a pan-FGFR inhibitor with an immunotherapy in China.

In December 2022, we announced the preliminary Phase II efficacy and safety results of fexagratinib in patients with urothelial carcinoma harboring FGFR2 or FGFR3 alterations in mainland China.

The preliminary efficacy results showed an ORR confirmed by IRC of 30.7% (4/13) in mUC patients with FGFR3 alteration (including mutations and/or fusions) and an IRC confirmed ORR of 44% (4/9) in patients with FGFR3 mutations, which is consistent with results from the prior BISCAY trial of fexagratinib in similar patient groups outside of China. The preliminary safety results showed that 80mg BID of fexagratinib was well-tolerated in Chinese patients, and no drug related grade 4 or above adverse effects were reported. These results support further development of fexagratinib in the ongoing Phase II trial.

In March 2022, we received ODD granted by the U.S. FDA to fexagratinib in gastric cancer.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK091 SUCCESSFULLY.

ABSK043

ABSK043 is an orally bioavailable, highly selective small molecule PD-L1 inhibitor being developed for the treatment of various cancers and potentially non-oncology indications. While anti-PD-1/anti-PD-L1 antibodies have revolutionized cancer treatment, the antibody-based immunotherapies carry a number of disadvantages such as high cost, lack of oral bioavailability, and immunogenicity, which could likely be improved with small molecule inhibitors. Pre-clinical data have demonstrated strong inhibition of PD-1/PD-L1 interaction by ABSK043, and rescue of PD-L1-mediated inhibition of T-cell activation. ABSK043 has also demonstrated strong anti-tumor efficacy and excellent safety profile in several pre-clinical models.

Current status

We are conducting a Phase I trial in Australia to assess the safety, tolerability and PK/PD profile of ABSK043 in patients with solid tumors. Patient enrollment is ongoing.

In March 2022, we received the IND approval for a Phase I trial of ABSK043 in the treatment of patients with malignant tumor in mainland China. In September 2022, we completed the dosing of the first patient in China. This trial (ABSK043-101) is the first clinical study of ABSK043 in China.

ABSK061

ABSK061 is a highly selective small molecule FGFR2/3 inhibitor. Pre-clinical research has shown that ABSK061 selectively inhibits FGFR2/3 over FGFR1 across various in vitro and cellular assays, with little activity against other kinases. Its high selectivity against FGFR2/3 and reduced FGFR1 activity could lead to an improved safety profile due to less off-target side effects, and potentially improved therapeutic window and efficacy as well as better opportunities for treating non-oncology indications. We believe that ABSK061 has the potential to be a second generation FGFR inhibitor with its improved selectivity over currently marketed FGFR inhibitors based on our pre-clinical data.

Current status

We have received IND approval in both mainland China and the U.S. to conduct Phase I clinical trials for ABSK061 in patients with solid tumors. In June 2022, we dosed the first patient. Patient enrollment is ongoing.

ABSK121

ABSK121 is a highly selective, next-generation small molecule FGFR inhibitor that targets both wild-type and mutants of FGFR1-3 including those that are resistant to the currently approved or clinical FGFR inhibitors. It could potentially bring clinical benefits to patients who relapsed or progressed after initial treatment with first-generation FGFR inhibitors. In pre-clinical studies, ABSK121 has demonstrated strong potency against wild-type and various mutations of FGFR1-3, and showed excellence in vivo efficacy in FGFR dependent and FGFR-mutant dependent models.

Current status

In November 2022, we obtained clinical trial approval from the U.S. FDA for ABSK121 and will launch the first Phase I clinical trial in humans for the treatment of advanced solid tumors.

ABSK081

ABSK081 (mavorixafor), also known as X4P-001, is a novel small molecule antagonist to CXCR4 and currently the only orally bioavailable CXCR4 modulator in clinical development globally, according to Frost & Sullivan. ABSK081 is a potential treatment option for various cancers in which CXCR4 and its ligand CXCL12 contribute to the tumor microenvironment (TME) that supports immune evasion, neoangiogenesis, and tumor metastasis. In July 2019, we entered into an exclusive license agreement with X4 Pharmaceuticals, Inc. ("**X4**") and obtained the rights for the development, manufacturing and commercialization of the licensed compound ABSK081 (mavorixafor) in mainland China, Taiwan, Hong Kong and Macau for any oncological indication and WHIM Syndrome in humans, excluding mozobil indications and any use for auto-HSCT treatment and allo-HSCT treatments.

Current status

In November 2021, our partner, X4, announced that it had completed patient enrollment in the Phase III clinical trial. In November 2022, positive top-line results were disclosed.

In mainland China, we are conducting a Phase Ib/II clinical trial of ABSK081 (mavorixafor) in combination with toripalimab from Junshi in TNBC patients in China. We dosed the first patient in July 2021. Patient enrollment has been completed.

IND-enabling candidates

ABSK051 is a small molecule CD73 inhibitor being developed for the treatment of various tumor types including lung cancer, pancreatic cancer and other cancers. It has demonstrated strong potency in inhibiting the activities of soluble and surface-expressed CD73. It has also shown strong efficacy in vivo in various animal models. We are currently conducting IND-enabling studies.

ABSK012 is an orally bioavailable, highly selective, next-generation small molecule FGFR4 inhibitor with strong potency against both wild-type and mutant FGFR4. In pre-clinical studies, ABSK012 has demonstrated strong activities in vitro and in cells against both wild-type FGFR4 and various FGFR4 mutants that are resistant to current FGFR4 inhibitors in clinical development, and excellent in vivo efficacy in FGF19-driven and FGFR4-mutant models. We are currently conducting IND-enabling studies.

ABSK112 is a next-generation EGFR-exon20 inhibitor with improved selectivity over wild-type EGFR and strong brain penetrating ability. EGFR-exon20 mutations occur in 3-5% of NSCLC patients, and are resistant to the currently available first, second and third generation EGFR inhibitors. Current clinical compounds targeting these mutations have limited therapeutic window due to limited selectivity against wild-type EGFR. Increased selectivity will likely lead to better target modulation and efficacy in clinical trials. ABSK112 demonstrates strong activity against EGFR-exon20 mutants and clear selectivity against wild-type EGFR in various cellular assays. It has efficacy and PD effects in mouse xenograft models bearing EGFR Exon20 mutation. We are currently conducting IND-enabling studies.

Business development activities

We have established a dedicated business development team to source and evaluate potential opportunities for licensing deals opportunities as well as strategic partnerships of various forms. Through business development activities, we aim to not only maximize the commercial value of our pipeline globally, but also expand the potential of our in-house drug discovery engine.

- In January 2022, we entered into a worldwide co-discovery collaboration with Lilly for the discovery, development and commercialization of novel small molecules against an undisclosed target with critical unmet medical needs. Under the agreement, Lilly will provide prior discovery information as well as additional disease knowledge and expertise to us, and we will be responsible for the discovery and development of molecules that modulate a novel and challenging drug target using our proprietary R&D platform. Upon achievement of the agreed endpoints, Lilly will have the right to further develop and commercialize the asset, and we will be eligible to receive up to US$258 million in potential payments based on the achievement of prespecified preclinical, clinical development and commercial milestones, as well as tiered royalties on sales.

- In February 2022, we announced a collaboration with BeiGene on the combination therapy of fexagratinib and tislelizumab, an anti-PD-1 antibody developed by BeiGene, for the treatment of urothelial cancer. In May 2022, we received the IND approval from NMPA to initiate a Phase II trial for the combination therapy. In November 2022, we completed the first patient enrollment in the Phase II clinical trial for fexagratinib in combination with tislelizumab.

- In March 2023, we entered into an exclusive out-license agreement with Allist for the research, development, manufacture, use, and sales of ABK3376 (a next-generation EGFR-TKI) in Greater China Region (Mainland China, Hong Kong, Macau, and Taiwan). We also granted Allist a time-limited option to expand the licensed territory worldwide in accordance with the terms and conditions agreed upon by both parties. The total deal size is up to US$187.90 million, including upfront development and sales milestones payments, plus tiered royalties on net sales.

Research and development

We believe R&D are critical to our future growth and our ability to remain competitive in the Chinese biopharmaceutical market. We are dedicated to enhancing our pipeline by leveraging our leading in-house R&D capabilities, which spans from early drug discovery to clinical development.

As at December 31, 2022, our R&D team consisted of approximately 200 employees and have extensive clinical development experience, with a particular focus on oncology. Among our R&D team members, over 68% have obtained at least post-graduate degrees, and approximately 21% hold Ph.D. degrees. Among our pre-clinical R&D team members, approximately 79% have obtained at least post-graduate degrees, and approximately 32% hold Ph.D. degrees.

Drug discovery and pre-clinical development

Our drug discovery effort is led by our co-founders, Dr. Xu Yao-Chang, Dr. Yu Hongping and Dr. Chen Zhui, who collectively have made contributions to dozens of discovery programs, a number of which led to successful commercialization, such as Ameile (almonertinib), Cymbalta (duloxetine), Balversa (erdafitinib), Reyvow (lasmiditan), Fu Laimei (PEG-loxenatide), Kisqali (ribociclib), Xinfu (flumatinib) and Venclexta (venetoclax).

We use various discovery and engineering technologies to discover and select our lead compounds with suitable pharmaceutical properties and market potential. Our drug discovery team collaborates with our CMC team at an early stage to complement each team's needs and to ensure continued knowledge sharing, regulatory compliance and a streamlined transition from discovery to development. Our drug discovery team also includes a translational medicine function that conducts biomarker discovery and bioinformatics data processing and analysis to facilitate our clinical studies. We conduct translational research to assess the effectiveness of treatment, evaluate different ways to customize therapies, and improve personalized medicine guidelines using the new data generated. These insights help further guide us toward new directions in novel drug and biomarker discovery.

Clinical development

Our clinical development team is led by Dr. Ji Jing, who received a M.D. degree from Fudan University and Shanghai Second Medical University, majoring in GI and liver disease. She has over 25 years of experience in early and late-stage clinical development in global pharmaceutical companies, serving as clinical development leader and head of therapy area. She has led and executed a wide range of functions, including medical, clinical operations, quality control, clinical research, clinical pharmacology and patient safety.

Our clinical development team manages all stages of our clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. We have entered into agreements with hospitals and principal investigators located in China, the U.S. and other regions that can support our clinical trials of different indications at different stages. We believe our experience in executing clinical trials helps us accelerate our drug development.

With the vision to address unmet medical needs of global patients, we have always been aiming for the global markets. We believe such going-global approach will maximize the commercial value of our assets, for which we own global rights. We have received 15 IND or clinical trial approvals in four countries and regions. Trials outside mainland China include a Phase Ib trial ongoing in the U.S. for pimicotinib, a Phase I trial ongoing in Australia for ABSK043, a Phase I trial ongoing in the U.S. for ABSK061, and two completed trials in Taiwan for irpagratinib Phase Ia and fexagratinib Phase I respectively.

Events after the Reporting Period

Subsequent to December 31, 2022, the significant events that took place are listed below:

Pimicotinib has been approved by the NMPA for a Phase II clinical study in patients with cGvHD. Pre-clinical data indicated that pimicotinib is a highly potent and selective small molecule inhibitor of CSF-1R that may play important roles for treating many human diseases including complications associated with transplantations.

Pimicotinib has also been granted the BTD from the U.S. FDA for the treatment of TGCT patients that are not amenable to surgery. This BTD approval is based on results from the Phase Ib clinical trial of TGCT cohort for pimicotinib.

ABK3376, a pre-clinical candidate was licensed out to Allist. ABK3376, which is a highly potent, selective, and brain-penetrating new-generation EGFR inhibitor, was discovered by our proprietary drug discovery platform. It can efficiently inhibit the C797S mutation occuring after third-generation EGFR-TKI resistance.

Future and Outlook

The 2022 has been challenging due to continuous regional outbreak of COVID-19 pandemic and strict zero-COVID policy. Shanghai has experienced a city-wide lockdown. Despite the challenges we faced during 2022, we have taken various measures to minimize the impact of COVID-19 on business operations and R&D activities.

Under the joint efforts of all departments of our Company, we were able to progress most of our business during lockdown without disruption. For instance, we managed to successfully submit IND application for fexagratinib combo study during the lockdown, and subsequently received IND approval before lockdown was over.

Looking forward into 2023, we will continue to advance our clinical and preclinical programs as planned and expect to release the next wave of proof-of-concept data during 2023. We also expect to submit IND applications for several pre-clinical assets.

Looking beyond 2023, as a company focused on discovery and development of differentiated therapies in cancer and targeted to treat critical unmet needs for patients in China and globally, we will continue to strive for our initial goals, which mainly comprise the following:

- We will continue to advance our clinical-stage compounds with quality and speed, and push forward the development of pre-clinical candidates.

- We will continue to expand our pipeline with innovative programs primarily focusing on first-in-class or best-in-class therapies, to address critical unmet medical needs for patients in China and globally, as always advocated in our mission statement.

- We will also continue to explore, evaluate and identify suitable business development opportunities so as to maximize the commercial value of our pipeline candidates.

Impact of COVID-19

During the first half of 2022, the PRC government has continuously stuck to the strict zero-COVID policy and imposed mandatory quarantine, closure of workplaces and facilities, travel restriction and other related measures to contain the spread and regional outbreak of the virus.

In particular, in response to the outbreak of COVID-19 in Shanghai, the PRC government adopted a city-wide lockdown. Disruption of hospitals in Shanghai caused minor impact on certain trials. However, given that our clinical trials are conducted in hospitals located in multiple cities across China and most of the clinical trial sites are located outside of Shanghai, there was no significant impact on the progress of our clinical trials due to the lockdown. We do not expect the pandemic to have any material impact on the overall clinical development plans in the long term.

Due to the closure of our lab in Zhangjiang area and the disruption of certain Contract Research Organisations (the "**CROs**") during Shanghai lockdown, some delays have occurred to our pre-clinical programs. During the lockdown, we kept monitoring the latest pandemic prevention and control policy and maintained continuous communication with relevant government authorities regarding resumption of business operation. In May 2022, we were included in the white list of enterprise resuming work and production issued by Shanghai municipal government and our lab successfully resumed operation afterwards, with most of the key R&D staff back to lab in mid-May. Since early June, we have fully resumed business operations in all aspects. As of the date of this announcement, the Chinese government had also lifted most of restrictive measures that were once in force.

II. FINANCIAL REVIEW

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

	2022	2021
	RMB'000	*RMB'000*
Revenue	**–**	22,682
Cost of sales	**–**	–
Gross profit	**–**	22,682
Other income and gains	**45,563**	43,587
R&D expenses	**(378,746)**	(226,126)
Administrative expenses	**(118,443)**	(124,777)
Other expenses	**(41,295)**	(80)
Fair value losses on convertible redeemable preferred shares	**–**	(1,524,320)
Finance costs	**(2,685)**	(959)
LOSS BEFORE TAX	**(495,606)**	(1,809,993)
Income tax expenses	**–**	–
LOSS FOR THE YEAR	**(495,606)**	(1,809,993)
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**774**	53,268
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of the Company	**199,493**	(60,895)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX	**200,267**	(7,627)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(295,339)**	(1,817,620)
Loss attributable to:		
Owners of the parent	**(495,606)**	(1,809,993)
Total comprehensive loss attributable to:		
Owners of the parent	**(295,339)**	(1,817,620)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT		
Basic and diluted		
For loss for the year	**RMB0.80**	RMB7.71

	2022 *RMB'000*	2021 *RMB'000*
NON-CURRENT ASSETS		
Property, plant and equipment	**32,364**	15,209
Right-of-use assets	**44,936**	54,085
Intangible assets	**4,505**	3,051
Other non-current assets	**27**	805
Total non-current assets	**81,832**	73,150
CURRENT ASSETS		
Prepayments and other receivables	**55,094**	35,876
Financial assets at fair value through profit or loss	**93,796**	–
Cash and bank balances	**2,258,827**	2,545,513
Total current assets	**2,407,717**	2,581,389
CURRENT LIABILITIES		
Other payables and accruals	**97,585**	64,676
Lease liabilities	**9,968**	8,862
Total current liabilities	**107,553**	73,538
NET CURRENT ASSETS	**2,300,164**	2,507,851
TOTAL ASSETS LESS CURRENT LIABILITIES	**2,381,996**	2,581,001
NON-CURRENT LIABILITIES		
Lease liabilities	**35,607**	44,942
Total non-current liabilities	**35,607**	44,942
Net assets	**2,346,389**	2,536,059
EQUITY		
Equity attributable to owners of the parent		
Share capital	**46**	46
Treasury shares	**(3)**	(5)
Other reserves	**2,346,346**	2,536,018
Total equity	**2,346,389**	2,536,059

Revenue. Revenue for the year ended December 31, 2022 was zero, while revenue for the year ended December 31, 2021 was RMB22.7 million which was attributed to an out-license upfront payment generated from one of our clinical candidates.

Other income and gains. Other income and gains increased by RMB2.0 million from RMB43.6 million for the year ended December 31, 2021 to RMB45.6 million for the year end December 31, 2022, primarily attributable to: 1) an increase in bank interest income by RMB18.1 million, resulting from an increase in our average cash and bank balances and an increase in interest rates of our time deposits; 2) a decrease in government subsidies by RMB3.5 million; and 3) a decrease in gain on disposal of an associate, resulting from a non-recurring gain of RMB5.9 million recognized from the disposal of a previous equity investment occurred in 2021.

Other income and gains

	2022	2021
	RMB'000	*RMB'000*
Bank interest income	**35,018**	16,938
Government grants	**10,545**	14,081
Gain on disposal of an associate	**–**	5,900
Foreign exchange gains	**–**	6,668
Total	**45,563**	43,587

Research and development expenses. R&D expenses increased by RMB152.6 million from RMB226.1 million for the year ended December 31, 2021 to RMB378.7 million for the year ended December 31, 2022, primarily attributable to: 1) increase in employee cost by RMB56.0 million due to continuous expansion of functions related to R&D; and 2) increase in third party contracting cost by RMB87.6 million as we advanced our clinical trials to later stage while expanding early discovery and research activities at the same time.

Research and development expenses

	2022	2021
	RMB'000	*RMB'000*
Employee cost	**167,917**	111,916
Third party contracting cost	**183,548**	95,998
Others	**27,281**	18,212
Total	**378,746**	226,126

Administrative expenses. Administrative expenses decreased by RMB6.4 million from RMB124.8 million for the year ended December 31, 2021 to RMB118.4 million for the year ended December 31, 2022, primarily attributable to: 1) an increase in employee cost by RMB18.3 million due to expansion of workforce in non-R&D related functions; 2) an decrease in third party advisory service cost by RMB22.2 million, mainly due to the absence of RMB27.6 million IPO related expenses, while partially offset by increased professional service fees.

Administrative expenses

	2022	2021
	RMB'000	*RMB'000*
Employee cost	**88,621**	70,339
Third party advisory service cost	**20,798**	43,007
Others	**9,024**	11,431
Total	**118,443**	124,777

Finance costs. Finance costs increased by RMB1.7 million from RMB1.0 million for the year ended December 31, 2021 to RMB2.7 million for the year ended December 31, 2022. The nature of the finance cost is the interest expense incurred on lease liabilities. Increase in finance cost for the year ended in December 31, 2022 is mainly due to the increase of interest on lease liabilities.

Other expenses. Other expenses increased by RMB41.2 million from RMB0.1 million for the year ended December 31, 2021 to RMB41.3 million for the year ended December 31, 2022, primarily due to the fluctuation of foreign exchange differences.

Fair value losses on convertible redeemable preferred shares. Fair value losses on convertible redeemable preferred shares decreased by RMB1,524.3 million from RMB1,524.3 million for the year ended December 31, 2021 to zero for the year ended December 31, 2022, primarily due to the convertible redeemable preferred shares had been converted into ordinary shares upon the listing of the Company's shares, and will not affect our financial performance in the subsequent financial years.

NON-IFRS MEASURE

To supplement the Group's Consolidated Financial Statements, which are presented in accordance with the IFRS, the Company also uses adjusted loss for the year and other adjusted figures as additional financial measures, which are not required by, or presented in accordance with, the IFRS. The Company believes that these adjusted measures provide useful information to shareholders and potential investors in understanding and evaluating the Group's consolidated results of operations.

Adjusted loss for the year represents the loss for the year excluding the effect of certain non-cash items and onetime events, namely the loss on fair value changes of the convertible redeemable preferred shares and share-based compensation cost. The term adjusted loss for the year is not defined under the IFRS. The use of this non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as substitute for analysis of, the Group's results of operations or financial condition as reported under IFRS. The Company's presentation of such adjusted figure may not be comparable to a similarly titled measure presented by other companies. However, the Company believes that this and other non-IFRS measures are reflections of the Group's normal operating results by eliminating potential impacts of items that the management do not consider to be indicative of the Group's operating performance, and thus facilitate comparisons of operating performance from period to period and company to company to the extent applicable.

The table below sets forth a reconciliation of the loss to adjusted loss during the periods indicated:

	2022	2021
	RMB'000	*RMB'000*
Loss for the year	**(495,606)**	(1,809,993)
Added:		
Fair value losses on convertible redeemable preferred shares	**–**	1,524,320
Share-based compensation cost	**110,121**	89,933
Adjusted loss for the year	**(385,485)**	(195,740)

The table below sets forth a reconciliation of the R&D expenses to adjusted R&D expenses during the periods indicated:

	2022	2021
	RMB'000	*RMB'000*
R&D expenses for the year	**(378,746)**	(226,126)
Added:		
Share-based compensation cost	**65,110**	49,811
Adjusted R&D expenses for the year	**(313,636)**	(176,315)

The table below sets forth a reconciliation of the administrative expenses to adjusted administrative expenses during the periods indicated:

	2022	2021
	RMB'000	*RMB'000*
Administrative expenses for the year	**(118,443)**	(124,777)
Added:		
Share-based compensation cost	**45,011**	40,122
Adjusted administrative expenses for the year	**(73,432)**	(84,655)

Liquidity

Liquidity and Financial Resources

The Group's cash and bank balances as at December 31, 2022 were RMB2,258.8 million, representing an decrease of 11% compared to RMB2,545.5 million for the year ended December 31, 2021. The decrease was primarily attributable to continuous expansion and rapid progress of various R&D pipelines as well as business operations, partially offset by impact from foreign exchange volatility.

Gearing ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. As at December 31, 2022, our gearing ratio was 6% (as at December 31, 2021: 4%).

Other Financial Information

Material Acquisition and Disposal of Subsidiaries, Associates and Joint Ventures

The Group had no material acquisitions and disposals of subsidiaries, associates and joint ventures during the Reporting Period.

Future Plans for Material Investments or Capital Assets

Save as disclosed in this announcement, we do not have any future plans for material investments or capital assets as at the date of this announcement.

Foreign Exchange Risk

Our financial statements are expressed in RMB, but certain of our financial assets measured at fair value through profit or loss 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.

Bank Loans and Other Borrowings

As at December 31, 2022, we did not have any bank loans or other forms of borrowings.

Contingent Liabilities

The Group had no material contingent liability as at December 31, 2022.

CORPORATE GOVERNANCE AND OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company is committed to maintaining high standards of corporate governance to safeguard the interests of the shareholders and to enhance corporate value and accountability. The Company has applied the principles and code provisions as set out in the Corporate Governance Code (the "**CG Code**") contained in Appendix 14 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited ("**Listing Rules**"). During the Reporting Period, the Board is of the opinion that the Company has complied with all the code provisions apart from the deviations below.

Code provision C.2.1 of the CG Code provides that the roles of the chairman of the Board (the "**Chairman**") and chief executive officer (the "**CEO**") should be separated and should not be performed by the same individual. As at the date of this announcement, the roles of the Chairman and the CEO of the Company are held by Dr. Xu Yao-chang ("**Dr. Xu**").

The Board believes that, in view of Dr. Xu's experience, personal profile and his roles in our Company as mentioned above, Dr. Xu is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our CEO. The Board also believes that the combined role of chairperson and CEO can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board.

Further, the decisions to be made by the Board require approval by at least a majority of our Directors and that the Board comprises two non-executive Directors and three independent non-executive Directors, which the Company believes that there are sufficient checks and balances in the Board. Dr. Xu and other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that they shall act for the benefit and in the best interest of the Company and will make decisions for the Group accordingly.

The Board will continue to review and consider splitting the roles of the Chairman and the CEO at the time when it is appropriate by taking into account the circumstances of the Group as a whole.

Code provision C.5.1 of the CG Code stipulates that the Board should meet regularly and board meeting should be held at least four times a year at approximately quarterly intervals. During the Reporting Period, only three regular board meetings were held to review and discuss the annual and interim results and operating performance, and considering and approving the overall strategies and policies of the Company. In the second quarter of 2022, Shanghai was locked down due to the outbreak of COVID-19 pandemic and the Board meeting of the second quarter was cancelled. The Company does not announce its quarterly results and hence the Board does not consider the holding of quarterly meetings as indispensable. During the Reporting Period, management of the Company has provided all members of the Board with monthly updates giving a balanced and understandable assessment of the Company's performance, position and prospects in sufficient detail.

Further information concerning the corporate governance practices of the Company will be set out in the corporate governance report in the annual report of the Company for the year ended December 31, 2022, which will be dispatched to the shareholders and published on the websites of the Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") and the Company in due course. 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.

The Board will examine and review, from time to time, the Company's corporate governance practices and operations in order to meet the relevant provisions under the Listing Rules.

Compliance with Model Code

The Company has adopted a code on terms no less exacting than the required standard set out in the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules (the "**Model Code**") as its code of conduct regarding dealings in the securities of the Company by the Directors, and the Group's employees who, because of his/her office or employment, are likely to possess inside information in relation to the Group or the Company's securities. Specific enquiries have been made to all the Directors and they have confirmed that they have complied with the Model Code during the Reporting Period. No incident of non-compliance with the Model Code by the employees was noted by the Company during the Reporting Period.

Use of Proceeds from the Global Offering

The shares of the Company were listed on the Stock Exchange on October 13, 2021 and the Company obtained net proceeds of approximately HK$1,674 million (after deducting the underwriting commissions and other estimated expenses in connection with the global offering and the exercise of the over-allotment option).

The net proceeds have been and will be utilized in accordance with the purposes set out in the prospectus of the Company dated September 30, 2021 under the section headed "Future Plans and Use of Proceeds". The table below sets out the planned allocations of the net proceeds and actual usage up to December 31, 2022:

	% of use of proceeds (Approximately)	**Net proceeds from the IPO** *(HK$ million)*	**Amount of unutilized net proceeds as at January 1, 2022** *(HK$ million)*	**Actual usage during the Reporting Period** *(HK$ million)*	**Unutilized net proceeds as of December 31, 2022** *(HK$ million)*	**Expected timeline for application of the Unutilized Proceeds**
Fund the ongoing and future R&D including planned clinical trials, preparation of registration filings, and future commercialization of our Core Product Candidate Irpagratinib (ABSK011)	19.7%	329.78	329.78	20.88	308.90	Expected to be fully utilized by December 31, 2024
Fund the ongoing and future R&D including planned clinical trials, preparation of registration filings and future commercialization of our Core Product candidate fexagratinib (ABSK091, AZD4547)	32.6%	545.72	545.72	28.34	517.38	Expected to be fully utilized by December 31, 2024
Fund our other clinical stage products and product candidates in our pipeline	28.0%	468.72	468.72	66.27	402.45	Expected to be fully utilized by December 31, 2024
Fund our pre-clinical research and studies, including continued development of our R&D platform and R&D of new pre-clinical candidates	8.4%	140.62	140.62	63.02	77.60	Expected to be fully utilized by December 31, 2024
Fund the construction of manufacturing facility in Shanghai	6.3%	105.46	105.46	20.25	85.21	Expected to be fully utilized by December 31, 2024
Working capital and general corporate purposes	5.0%	83.70	83.70	20.94	62.76	Expected to be fully utilized by December 31, 2024
Total	100%	1,674.00	1,674.00	219.70	1,454.30	

Note:

(1) Net IPO proceeds were received in Hong Kong dollars and translated to Renminbi for application planning.

Significant Investment Held

During the Reporting Period, the Group did not hold any significant investments.

Purchase, Sale or Redemption of Listed Securities

In February 2022 the Company repurchased in total 804,000 shares on the Stock Exchange for an aggregate consideration of approximately HK$4.7 million before expenses. The highest price per share paid and the lowest price per share paid were HK$5.9 and HK$5.69 respectively. All of the repurchased shares were subsequently cancelled on March 14, 2022.

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

FINAL DIVIDEND

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2022.

CLOSURE OF REGISTER OF MEMBERS

The register of members of the Company will be closed from June 9, 2023 to June 14, 2023 (both days inclusive), in order to determine the eligibility of the holders of shares to attend and vote at the annual general meeting (the "**AGM**") to be held on Wednesday, June 14, 2023. The holder of shares whose names appear on the share register of members of the Company on June 14, 2023 (Wednesday) will be entitled to attend and vote at the AGM. In order to be eligible to attend and vote at the AGM, all transfer accompanied by the relevant share certificates and transfer forms must be lodged with the Company's share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong before 4:30 p.m. on Thursday, June 8, 2023.

SCOPE OF WORK OF THE COMPANY'S AUDITOR

The figures in respect of the Group's consolidated statement of financial position, statement of profit or loss and other comprehensive income, and the related notes thereto for the year ended December 31, 2022 as set out in this announcement have been agreed by the Company's auditors, Ernst & Young, to the amounts set out in the Group's consolidated financial statements for the year. The work performed by the Company'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 Company's auditors on this announcement.

AUDIT COMMITTEE REVIEW OF FINANCIAL STATEMENTS

The Audit Committee has considered and reviewed the consolidated annual results of the Group for the year ended December 31, 2022 and the accounting principles and practices adopted by the Group, and has discussed with management on issues in relation to internal control, risk management and financial reporting. The Audit Committee is of the opinion that the consolidated annual results of the Group for the year ended December 31, 2022 are in compliance with the relevant accounting standards, laws and regulations.

PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT

This results announcement is published on the Company's website (www.abbisko.com) and the website of the Stock Exchange.

The 2022 annual report of the Company containing all relevant information required under the Listing Rules will be published on the aforementioned websites and dispatched to the shareholders of the Company in due course.

By order of the Board
Abbisko Cayman Limited
Dr. Xu Yao-Chang
Chairman

Shanghai, March 15, 2023

As at the date of this announcement, the board of directors of the Company comprises Dr. Xu Yao-Chang, Dr. Yu Hongping and Dr. Chen Zhui as executive directors; Dr. Xia Gavin Guoyao and Ms. Tang Yanmin as non-executive directors; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Mr. Wang Lei as independent non-executive directors.