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Laekna, Inc.

來凱醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2105)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2024

The Board of Laekna, Inc. is pleased to announce the consolidated annual results of the Group for the year ended December 31, 2024, together with comparative figures for the year ended December 31, 2023, as follows.

In this announcement, “we” and “our” refer to the Company and where the context otherwise requires, the Group. Certain amounts and percentage figures included in this announcement have been subject to rounding adjustments or have been rounded to one or two decimal places. Any discrepancies in any table, chart or elsewhere between totals and sums of amounts listed therein are due to rounding issues.

BUSINESS HIGHLIGHTS

We have made significant progress with respect to the clinical and pre-clinical developments of our drug candidate assets. For the year ended December 31, 2024, we made the following milestones and achievements:

Advancing The Clinical Trials

LAE102 in Obesity, Phase I

LAE102 is our internally discovered monoclonal antibody against ActRIIA. Blocking Activin-ActRII pathway could promote muscle regeneration and decrease fat mass, this positions LAE102 as a promising drug candidate for achieving quality weight control. We submitted IND applications to both CDE and FDA for LAE102 in obesity indication in the first quarter of 2024 and obtained approvals of the same in the second quarter of 2024. We commenced the Phase I clinical study of LAE102 in June 2024 in China which was ahead of our planned schedule. The Phase I clinical study is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of the LAE102.

In November 2024, the Group entered into a clinical collaboration agreement with Eli Lilly and Company (“**Lilly**”) (NYSE: LLY) to support and accelerate global clinical development of LAE102 for the treatment of obesity. Lilly will be responsible for the execution and funding of a Phase I study in the U.S. (the “**U.S. Phase 1 Clinical Trial**”). The Group retains global rights for LAE102. The U.S. Phase 1 Clinical Trial is expected to commence in the second quarter of 2025.

By the end of December 2024, the Group successfully completed the single ascending dose part of the Phase I clinical study (the “**SAD Study**”) of LAE102 in China for the treatment of obesity. The SAD Study enrolled a total of 64 healthy subjects including 5 intravenous cohorts and 3 subcutaneous cohorts.

The SAD Study data of LAE102 demonstrated an encouraging safety and tolerability profile, with no serious adverse events and no discontinuations due to adverse events. All treatment emergent adverse events reported to date were very well tolerated, with the majority of them being reported as mild (grade 1) lab test abnormality without any clinical symptoms or signs. There is no reported case of diarrhea. Obvious target engagements and expected pharmacodynamic biomarker changes have been observed. Single doses of LAE102 resulted in significant and sustained increase in activin A level, indicating a robust target engagement. The duration of target engagement correlated to the dose level. The detailed study results will be presented at an international scientific conference in 2025. The positive outcomes of the SAD Study results have established a solid foundation for the Phase I multiple ascending dose study (the “**MAD Study**”).

The Group targets to commence the Phase I MAD Study in China in March 2025. The Phase I MAD Study in China is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of LAE102, administered subcutaneously, in 60 overweight/obese subjects. The Group aims to bring this precision therapy to overweight and obese patients who are in need of novel treatment options for achieving quality weight control.

Laekna team has accumulated tremendous experience and extensive knowhow in this specific field and is developing, in addition to LAE102, more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor against ActRIIA/IIB. Both are our internally discovered antibodies for muscle and other disease indications. IND-enabling studies of both antibodies have been initiated in 2024. We target to submit IND applications for LAE103 and LAE123 in the second quarter and the fourth quarter of 2025 respectively.

LAE002 (afuresertib) +Fulvestrant in HR+/HER2-breast cancer, Phase III

The results of our Phase Ib study in this combination therapy have shown promising anti-cancer efficacy with a well-tolerated safety profile. The data of this study were presented during a poster spotlight session at the 2023 San Antonio Breast Cancer Symposium (SABCS) in December 2023. The Group also presented the updated clinical data of all enrolled subjects and the subjects with positive biomarker in this Phase Ib study as a poster presentation at the European Society for Medical Oncology (ESMO) Congress in Barcelona, Spain in September 2024.

As of the data cut-off date of August 27, 2024, results of the Phase Ib study in all 31 subjects and in a subgroup with PIK3CA/AKT1/PTEN alterations from the U.S. and China demonstrated promising anti-cancer efficacy with a well-tolerated safety profile. Among the 18 subjects with PIK3CA/AKT1/PTEN-alterations, the confirmed objective response rate was 33.3%, the clinical benefit rate was 66.7%, and the median PFS was 7.3 months.

The Group commenced the Phase III clinical trial AFFIRM-205 in China for LAE002 (afuresertib, an oral AKT inhibitor) plus fulvestrant in patients with PIK3CA/AKT1/PTEN alterations and HR+/HER2- locally advanced or metastatic breast cancer (“**LA/mBC**”) (the “**Phase III Clinical Trial AFFIRM-205**”) in May 2024, which was ahead of our planned schedule. The Phase III Clinical Trial AFFIRM-205 is a multi-center, randomized, double-blind, placebo-controlled pivotal study to further assess the anti-tumor efficacy and safety of the combination therapy. Study recruitment is on track. The Group targets to complete subject enrollment in the fourth quarter of 2025 and to submit new drug application (“**NDA**”) to CDE in the first half of 2026.

LAE002 (afuresertib) +LAE001/prednisone in mCRPC, Phase II

We initiated a Phase II multi-regional clinical trial of the study of LAE002 (afuresertib, an AKT inhibitor) plus LAE001 (CYP17A1/CYP11B2 dual inhibitor) (“**LAE201**”) in patients with metastatic castration-resistant prostate cancer (“**mCRPC**”) following standard of care (“**SOC**”) treatment in the U.S. in June 2021, and South Korea in September 2022. The trial is an open-label, dose-escalation and dose expansion study to assess the efficacy and safety of the combination candidate. The study demonstrated promising treatment benefit for mCRPC patients. As of November 21, 2023, 40 subjects who progressed on 1–3 lines of standard treatments, including at least 1 line of abiraterone, or the second generation of AR antagonists, had been enrolled in the recommended Phase II dose group. The median rPFS was 8.1 months. This is a significant improvement compared to the median rPFS of 2 to 4 months of mCRPC patients under the standard treatments historically. The combination therapy was generally tolerable with manageable treatment emergent adverse events and recoverable after routine treatments.

Design of the Phase III pivotal trial of LAE201 in patients with mCRPC following SOC treatment has been discussed with FDA. In May 2024, the Group obtained approval from FDA for the protocol of this Phase III clinical trial. We plan to pursue strategic partnerships to accelerate the development and commercialization of LAE002 (afuresertib) and LAE001 to address the great unmet medical need for cancer therapies.

LAE002 (afuresertib) +Paclitaxel for PROC (PROFECTA-II), Phase II

We have initiated a global MRCT Phase II trial (PROFECTA-II) in both the U.S. and China to treat 150 Platinum-Resistant Ovarian Cancer (“**PROC**”) patients with LAE002 (afuresertib) plus paclitaxel. Top-line data of the global MRCT Phase II trial (PROFECTA-II) was announced in January 2024. The study showed reduced risk of disease progression or death (progression-free survival; PFS) with a hazard ratio (HR) of 0.744 (95% CI: 0.502–1.102) but missed statistical significance. For biomarker subgroup with phospho-AKT positive, IHC>1, (37%), the study data demonstrated that LAE002 (afuresertib) combination arm significantly improved PFS, and the median PFS is 5.4m vs 2.9m with HR of 0.352 (95% CI: 0.125–0.997). We plan to pursue strategic partnerships to support further development of this program.

Pre-clinical candidates (PCC)

For the year ended December 31, 2024, IND-enabling studies of LAE103 and LAE123 have been initiated. We target to submit IND applications for LAE103 and LAE123 in the second quarter and the fourth quarter of 2025 respectively.

In the oncology area, LAE118, a PI3K α mutant-selective inhibitor, has advanced to IND-enabling study in the fourth quarter of 2024. IND application for LAE120, an USP1 inhibitor, was filed with FDA in January 2025 and we received SMP (Study May Proceed) from FDA in February 2025. PCC declaration for LAE122, a WRN mutant-selective inhibitor, was also completed in March 2025.

Expected Upcoming Milestones

About LAE102

- Q1 2025- To commence Phase I MAD Study in China
- Q2 2025- To commence U.S. Phase 1 Clinical Trial
- 2025- To present LAE102 Phase I SAD data at a scientific conference

About AFFIRM-205

- Q4 2025- To complete subject enrollment of AFFIRM-205 Phase III China trial

Other Targeting ActRII Receptors

- Q2 2025- To submit IND application for LAE103
- Q4 2025- To submit IND application for LAE123

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Research and development expenses	215,115	230,485
Administrative expenses	74,058	75,878
Fair value changes on financial instruments issued to investors	–	71,210
Loss for the year	254,296	368,814
Total comprehensive loss for the year	242,949	458,674

Our research and development expenses decreased by RMB15.4 million or 6.7% from RMB230.5 million in 2023 to RMB215.1 million in 2024. Such decrease was primarily attributable to the fact that the Group mainly focused on the prioritized clinical programs during the year ended December 31, 2024.

Our administrative expenses decreased by RMB1.8 million or 2.4% from RMB75.9 million in 2023 to RMB74.1 million in 2024. Such decrease was primarily attributable to the fact that, during the Reporting Period, the Group did not record any listing expenses as the Company's shares were successfully listed on the Main Board of the Stock Exchange in June 2023 and the listing expenses were fully recorded by the end of 2023.

Fair value changes on financial instruments issued to investors were related to preferred shares. All preferred shares were converted into ordinary shares of the Company upon completion of the Listing. Thus, no such losses were incurred during the Reporting Period.

**CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER
COMPREHENSIVE INCOME**

For the year ended December 31, 2024

(Expressed in Renminbi)

	<i>Note</i>	2024 RMB'000	2023 <i>RMB'000</i>
Other income	4	38,169	16,742
Other losses		(268)	(6,256)
Administrative expenses		(74,058)	(75,878)
Research and development expenses		(215,115)	(230,485)
Loss from operations		(251,272)	(295,877)
Finance costs	5(a)	(3,024)	(1,727)
Fair value changes on financial instruments issued to investors		—	(71,210)
Loss before taxation	5	(254,296)	(368,814)
Income tax	6	—	—
Loss for the year		(254,296)	(368,814)
Other comprehensive income for the year			
(after tax and reclassification adjustments)			
<i>Item that will not be reclassified to</i>			
<i>profit or loss:</i>			
Exchange differences on translation of financial statements of the Company		28,683	(79,050)
<i>Item that may be reclassified subsequently to</i>			
<i>profit or loss:</i>			
Exchange differences on translation of financial statements of foreign subsidiaries		(17,336)	(10,810)
Total comprehensive income for the year		(242,949)	(458,674)
Loss per share			
Basic and diluted (<i>RMB</i>)	7	(0.71)	(1.68)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As of December 31, 2024

(Expressed in Renminbi)

	<i>Note</i>	2024 RMB'000	2023 RMB'000
Non-current assets			
Property, plant and equipment		2,686	4,506
Intangible assets	8	125,108	124,229
Right-of-use assets		4,774	6,510
Other non-current assets		14,068	9,009
		<u>146,636</u>	<u>144,254</u>
Current assets			
Prepayments and other receivables		13,368	9,114
Time deposits	9	163,611	338,120
Cash and cash equivalents	10	636,422	440,815
		<u>813,401</u>	<u>788,049</u>
Current liabilities			
Bank loans	11	99,010	49,400
Other payables	12	47,418	68,445
Lease liabilities		2,045	1,917
		<u>148,473</u>	<u>119,762</u>
Net current assets		<u>664,928</u>	<u>668,287</u>
Total assets less current liabilities		<u>811,564</u>	<u>812,541</u>
Non-current liabilities			
Lease liabilities		3,272	5,069
Deferred income		3,500	3,500
		<u>6,772</u>	<u>8,569</u>
NET ASSETS		<u>804,792</u>	<u>803,972</u>
CAPITAL AND RESERVES			
Share capital		28	27
Treasury shares		(2)	(2)
Reserves		804,766	803,947
TOTAL EQUITY		<u>804,792</u>	<u>803,972</u>

CONSOLIDATED CASH FLOW STATEMENT

For the year ended December 31, 2024

(Expressed in Renminbi)

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Operating activities		
Cash used in operations	<u>(278,303)</u>	<u>(295,603)</u>
Net cash used in operating activities	<u>(278,303)</u>	<u>(295,603)</u>
Investing activities		
Payment for purchase of property, plant and equipment	(164)	(864)
Proceeds from sale of property, plant and equipment	4	–
Payment for purchase of intangible assets	(1,749)	(449)
Decrease/(increase) in time deposits with original maturity over three months	176,962	(338,120)
Interest received from bank deposits	33,139	13,988
Payment for purchase of wealth management products	–	(150,280)
Proceeds from redemption of wealth management products	–	152,564
Net cash generated from/(used in) investing activities	<u>208,192</u>	<u>(323,161)</u>
Financing activities		
Proceeds from bank loans	99,010	54,400
Repayment of bank loans	(49,400)	(24,960)
Interest paid for bank loans	(2,732)	(1,359)
Proceeds from issuance of ordinary shares by placing, net of issuance costs	213,159	–
Proceeds from issuance of ordinary shares through initial public offering, net of issuance costs	–	709,794
Payment for capital element of lease liabilities	(1,669)	(1,533)
Payment for interest element of lease liabilities	(292)	(368)
Net cash generated from financing activities	<u>258,076</u>	<u>735,974</u>

	<i>Note</i>	2024 RMB'000	2023 <i>RMB'000</i>
Net increase in cash and cash equivalents		187,965	117,210
Cash and cash equivalents at January 1	<i>10</i>	440,815	323,070
Effect of foreign exchange rate changes		<u>5,543</u>	<u>535</u>
Cash and cash equivalents at December 31	<i>10</i>	<u><u>634,323</u></u>	<u><u>440,815</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1 GENERAL INFORMATION

The Company was incorporated in the Cayman Islands on July 29, 2016 as an exempted company with limited liability under the law of the Cayman Islands.

The Company is an investing holding company. The Group is principally engaged in discovering, development and commercialising innovative therapies for cancer, metabolic diseases and liver fibrosis in the PRC, the U.S. and South Korea.

The Company's shares were listed on the Main Board of The Stock Exchange on June 29, 2023.

2 BASIS OF PREPARATION

The consolidated financial statements for the year ended December 31, 2024 comprise the Company and its subsidiaries.

The consolidated financial statements have been prepared in accordance with all applicable IFRSs using the historical cost basis except that the assets and liabilities are stated at their fair value.

The financial information relating to the financial year ended December 31, 2024 that is included in this preliminary annual results announcement does not constitute the Group's annual consolidated financial statements for that financial year but is derived from those financial statements.

3 CHANGES IN ACCOUNTING POLICIES

The Group has applied the following amendments to IFRSs issued by the IASB to these financial statements for the current accounting period:

- Amendments to IAS 1, *Presentation of financial statements — Classification of liabilities as current or non-current* (“**2020 amendments**”) and amendments to IAS 1, *Presentation of financial statements — Non-current liabilities with covenants* (“**2022 amendments**”)
- Amendments to IFRS 16, *Leases — Lease liability in a sale and leaseback*
- Amendments to IAS 7, *Statement of cash flows* and IFRS 7, *Financial instruments: Disclosures — Supplier finance arrangements*

None of these amendments have had a material impact on how the Group's results and financial position for the current or prior periods have been prepared or presented. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

4 OTHER INCOME

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Interest income from bank deposits	37,645	13,988
Realised gain on wealth management products	–	2,284
Government grants	524	470
	<u>38,169</u>	<u>16,742</u>

5 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging/(crediting):

(a) Finance costs

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Interest on bank loans	2,732	1,359
Interest on lease liabilities	292	368
	<u>3,024</u>	<u>1,727</u>

(b) Staff costs

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Salaries, wages and other benefits	99,248	100,305
Contributions to defined contribution retirement plan (i)	5,167	5,102
Equity settled share-based payment expenses	30,307	28,293
	<u>134,722</u>	<u>133,700</u>

(c) Other items

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Amortisation of intangible assets	2,127	1,864
Depreciation charge		
— property, plant and equipment	1,286	1,632
— right-of-use assets	1,736	1,736
	<u>3,022</u>	<u>3,368</u>
Listing expenses	—	12,953
Auditors' remuneration		
— audit services	3,000	3,000
— tax services	32	24
	<u>3,032</u>	<u>3,024</u>
Research and development expenses (ii)	215,115	230,485
Net foreign exchange losses	254	4,182

(i) The full-time employees of the Group are entitled to various government-sponsored defined-contribution retirement plans. The Group contributes on a monthly basis to these funds based on certain percentages of the salaries of the employees, subject to certain ceiling. The Group's liability in respect of these funds is limited to the contributions payable in each year.

(ii) During the year ended December 31, 2024, research and development expenses included staff costs, depreciation and amortisation expenses of RMB83,459,000 in total (2023: RMB92,373,000), in which the respective amounts were also disclosed separately above.

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.

(i) The Cayman Islands

Pursuant to the rules and regulations of the Cayman Islands, the Company is currently not subject to income tax.

(ii) Hong Kong, China

The Company's subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at 16.5% of the estimated assessable profits. No provision for Hong Kong profits tax had been made for the years ended December 31, 2024 and 2023 as there were no assessable profits.

(iii) The U.S.

The Company's subsidiary incorporated in the U.S. is subject to Federal Tax at a rate of 21% and State Profits Tax at a rate of 0.75% — 9.50% (2023: 0.75% — 9.50%). Operations in the U.S. have incurred net accumulated operating losses for income tax purposes, and no income tax provisions had been made for the years ended December 31, 2024 and 2023.

(iv) Chinese Mainland

Pursuant to the Corporate Income Tax Law of Chinese Mainland (the "CIT"), the Company's Chinese Mainland subsidiaries are subject to the CIT at a rate of 25%.

According to the new tax incentive policies promulgated by the State Tax Bureau of Chinese Mainland in March 2023, effective from January 1, 2023, an additional 100% of qualified research and development expenses incurred is allowed to be deducted from taxable income.

7 LOSS PER SHARE

The calculation of basic loss per share is based on the loss attributable to ordinary equity shareholders of the Company of RMB254,296,000 (2023: RMB368,814,000) and the weighted average of 357,626,000 ordinary shares (2023: 219,592,000 shares) in issue during the year.

The calculation of diluted loss per share for the years ended December 31, 2024 and 2023 has not included the potential effects of share options and restricted share units issued by the Company, as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended December 31, 2024 and 2023 are the same as basic loss per share.

8 INTANGIBLE ASSETS

	In-licensed rights <i>RMB'000</i>	Software <i>RMB'000</i>	Total <i>RMB'000</i>
Cost:			
At January 1, 2023	118,698	6,153	124,851
Additions	–	449	449
Exchange adjustments	2,013	–	2,013
	<u>120,711</u>	<u>6,602</u>	<u>127,313</u>
At December 31, 2023 and January 1, 2024	120,711	6,602	127,313
Additions	–	322	322
Transfers	–	883	883
Exchange adjustments	1,801	–	1,801
	<u>122,512</u>	<u>7,807</u>	<u>130,319</u>
At December 31, 2024	122,512	7,807	130,319
Accumulated amortisation:			
At January 1, 2023	–	(1,220)	(1,220)
Charge for the year	–	(1,864)	(1,864)
	<u>–</u>	<u>(3,084)</u>	<u>(3,084)</u>
At December 31, 2023 and January 1, 2024	–	(3,084)	(3,084)
Charge for the year	–	(2,127)	(2,127)
	<u>–</u>	<u>(5,211)</u>	<u>(5,211)</u>
At December 31, 2024	<u>–</u>	<u>(5,211)</u>	<u>(5,211)</u>
Net book value:			
At December 31, 2024	<u>122,512</u>	<u>2,596</u>	<u>125,108</u>
At December 31, 2023	<u>120,711</u>	<u>3,518</u>	<u>124,229</u>

In-licensed rights

The balance of in-licensed rights represents payments made to acquire development and commercialisation rights of drug products from third parties and are not ready for commercial use. Due to the inherent uncertainties in the research and development processes, these assets are particularly at risk of impairment if the projects are not expected to result in commercialised products. Key terms of these licenses are set out below:

(i) *LAE001*

On June 30, 2017, the Group entered into a license agreement with Novartis Pharma AG (“**Novartis**”), pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the licensed product LAE001 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD1 million (equivalent to RMB6.6 million) and granted 776,437 ordinary shares of the Company to Novartis (equaling to 7,764,370 shares after adjusting for the effect of the share subdivision upon the Listing). The Group capitalised an amount of USD1.8 million (equivalent to RMB12.2 million) in total. The Group also agreed to make regulatory milestone payments, as well as royalty payments on net sales to Novartis.

(ii) *LAE002 (afuresertib) & LAE003*

On May 9, 2018, the Group entered into a license agreement with Novartis, pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the licensed products LAE002 (afuresertib) and LAE003 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD5 million (equivalent to RMB31.9 million) and granted 165,200 ordinary shares of the Company to Novartis (equaling to 1,652,000 shares after adjusting for the effect of the share subdivision upon the Listing). The Group capitalised an amount of USD5.2 million (equivalent to RMB33.5 million) in total. The Group also agreed to make clinical trial milestone payments, regulatory milestone payments, sales milestone payments, as well as royalty payments on net sales to Novartis.

(iii) *LAE005*

On February 4, 2020, the Group entered into a license agreement with Novartis, pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the products LAE005 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD10 million (equivalent to RMB69.4 million) to Novartis and capitalised such payment. The Group also agreed to make clinical trial milestone payments, regulatory milestone payments, sales milestone payments, as well as royalty payments on net sales to Novartis.

(iv) *Impairment test*

Intangible assets not yet ready for commercial use are tested annually based on the recoverable amount of the CGU to which the intangible asset is related. The appropriate CGU is at the product level. The annual impairment test was performed for each drug by engaging an independent qualified professional valuer to estimate fair value less costs of disposal as the recoverable amount of each drug. The fair value is based on the multi-period excessive earning method and the Group estimated the forecast period till year 2035 for each drug based on the timing of clinical development and regulatory approval, commercial ramp up to reach expected peak revenue potential, and the length of exclusivity for each product. The estimated revenue of each drug is based on management's expectations of timing of commercialization. The costs and operating expenses are estimated as a percentage over the revenue forecast period based on the current margin levels of comparable companies with adjustments made to reflect the expected future price changes. The discount rates used are post-tax and reflect the general business and market risk of the Group. The discount rates are derived from capital asset pricing model by taking applicable market data into account, such as risk free rate, market premium, beta, company specific risk and size premium, etc.

The key assumptions used in estimating the recoverable amount are as follows:

	2024	2023
<i>LAE001</i>		
Discount rate	17%	18%
Revenue growth rate	-3% to 77%	-12% to 83%
Recoverable amount of CGU (<i>in RMB million</i>)	203.3	724.2
<i>LAE002 (afuresertib) & LAE003</i>		
Discount rate	17%	18%
Revenue growth rate	-1% to 237%	-7% to 523%
Recoverable amount of CGU (<i>in RMB million</i>)	1,908.4	963.6
<i>LAE005</i>		
Discount rate	17%	18%
Revenue growth rate	-6% to 17%	-15% to 24%
Recoverable amount of CGU (<i>in RMB million</i>)	113.8	278.0

Based on the result of the above assessment, there were no impairment for the in-licensed rights as at December 31, 2024 and 2023.

9 TIME DEPOSITS

	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Bank deposits with original maturity over three months	161,158	338,120
Accrued interest	2,453	-
	<u>163,611</u>	<u>338,120</u>

10 CASH AND CASH EQUIVALENTS

	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Cash at banks	194,172	171,626
Deposits with banks	440,151	269,189
	<u>634,323</u>	<u>440,815</u>
Accrued interest	2,099	-
	<u>636,422</u>	<u>440,815</u>

As at December 31, 2024, cash and cash equivalents of the Group situated in Chinese Mainland amounted to RMB259,738,000 (2023: RMB207,172,000). Remittance of funds out of Chinese Mainland is subject to relevant rules and regulations of foreign exchange control.

11 BANK LOANS

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Unsecured bank loans due within 1 year	<u>99,010</u>	<u>49,400</u>

As at December 31, 2024, unsecured bank loans carried interest at annual rates ranging from 3.20% to 4.10% (2023: 3.40% to 4.35%) per annum and were all repayable within one year.

12 OTHER PAYABLES

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Payroll payables	13,456	14,279
Accrued research and development expenses	29,048	42,939
Other payables and accrued charges	<u>4,914</u>	<u>11,227</u>
	<u>47,418</u>	<u>68,445</u>

13 DIVIDENDS

The directors of the Company did not propose any payment of dividend for the year ended December 31, 2024 (2023: nil).

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a science-driven, clinical-stage biotechnology company committed to bringing novel therapeutics to patients with metabolic diseases, cancer and liver fibrosis around the world. We focus on specific fields where we have accumulated tremendous experience and extensive know-how. As of December 31, 2024, we have initiated seven clinical trials for LAE102, LAE002 (afuresertib), LAE001 and LAE005 to address unmet medical needs in obesity and cancers.

We have assembled a seasoned management team with extensive experience and expertise covering the full cycle of drug discovery and development process, from pre-clinical asset discovery, clinical trial design and execution to regulatory process management and drug manufacturing. As of December 31, 2024, we were supported by a talented R&D team consisting of 61 employees, with 14 holding doctorate degrees and 32 holding master's degrees. Our core management team has established a long track record of accomplishment, leadership and deep knowledge in their respective fields.

Blocking Activin-ActRII pathway could promote muscle regeneration and decrease fat mass, this positions LAE102 as a promising drug candidate for achieving quality weight control. Laekna team has accumulated tremendous experience and extensive knowhow in this specific field and is developing, in addition to LAE102, more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor against ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle and other disease indications.

In the cancer area, we have built a comprehensive portfolio of drug candidates, including LAE002 (afuresertib), LAE001 and other seven pre-clinical drug candidates. LAE002 (afuresertib) is a potent AKT inhibitor that inhibits all three AKT isoforms (AKT1, AKT2 and AKT3) as well as one of the two AKT inhibitors in late-stage development for breast and prostate cancer globally. LAE002 (afuresertib) has demonstrated several superior features compared to other AKT inhibitors, including higher efficacy, better potency, more significant tumor inhibition exposure and a better safety profile, based on the public data. Capivasertib is the first approved AKT inhibitor from AstraZeneca, which FDA approved for HR+/HER2- breast cancer in November 2023. With the promising efficacy data from our LAE002 (afuresertib) Phase Ib study for HR+/HER2- breast cancer, the Group has initiated the Phase III pivotal study in China. The first subject in this Phase III study was enrolled in May 2024 which was ahead of our planned schedule. The Group plans to bring this precision therapy to HR+/HER2- LA/mBC patients who are in need of novel treatment options.

We plan to pursue strategic partnerships to accelerate the development and commercialization of our drug candidates to address the great unmet medical needs.

MARKET OPPORTUNITIES IN OBESITY AND CANCER TREATMENTS

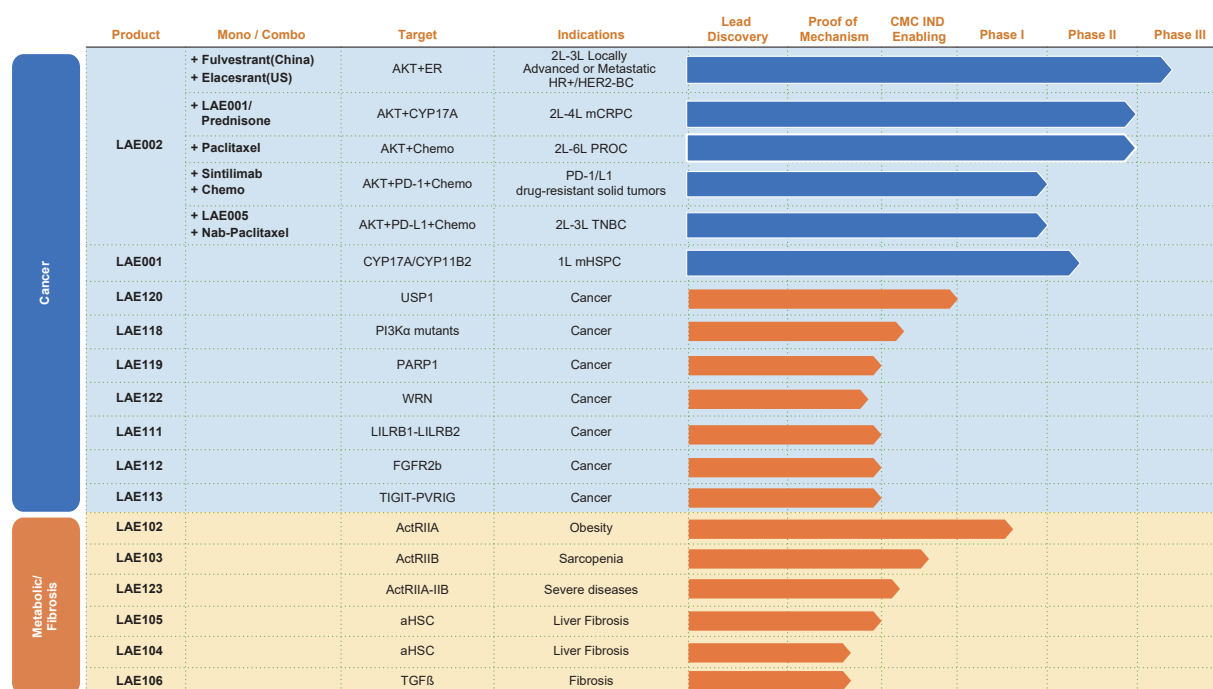
Globally, the number of people living with obesity is set to reach over 1.2 billion by 2030¹. The causes of obesity are complex and, so often, it puts people on a path to other diseases — not only diabetes, but also heart and liver diseases, cancers and many more. There are growing understandings of the critical need to treat obesity among both the medical community and the public, while an increasing number of people living with such disease are actively seeking support.

Although the field of cancer treatment has progressed significantly in the past decade, a significant proportion of cancer patients find themselves in the absence of effective or safe treatments. The quality of life of those patients is severely affected, primarily attributable to SOC treatment resistance and/or intolerable toxicity, resulting in a large unmet medical need and a socioeconomic burden. Among those cancers of unmet medical need, HR+/HER2- metastatic breast cancer (HR+/HER2- mBC), mCRPC, PROC and triple negative breast cancer (TNBC) are some of the diseases with limited SOC options and unsatisfactory treatment outcomes.

¹ World Obesity Federation, 2023b

PIPELINE

The following chart summarizes the development status of our clinical and pre-clinical stage drug candidates as of the date of this announcement:



BUSINESS REVIEW

During the year ended December 31, 2024, the Company has made significant progress with respect to its drug candidate pipeline and business operations, including the following milestones and achievements.

LAE102 in Obesity, Phase I

LAE102 is our internally discovered monoclonal antibody against ActRIIA. Blocking Activin-ActRII pathway could promote muscle regeneration and decrease fat mass, this positions LAE102 as a promising drug candidate for achieving quality weight control. We submitted IND applications to both CDE and FDA for LAE102 in obesity indication in the first quarter of 2024 and obtained approvals of the same in the second quarter of 2024. We commenced the Phase I clinical study of LAE102 in June 2024 in China which was ahead of our planned schedule. The Phase I clinical study is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of the LAE102.

In November 2024, the Group entered into a clinical collaboration agreement with Lilly to support and accelerate global clinical development of LAE102 for the treatment of obesity. Lilly will be responsible for the execution and funding of a Phase I study in the U.S. (the “**U.S. Phase 1 Clinical Trial**”). The Group retains global rights for LAE102. The U.S. Phase 1 Clinical Trial is expected to commence in the second quarter of 2025.

By the end of December 2024, the Group successfully completed the Phase I SAD study of LAE102 in China for the treatment of obesity. The SAD Study enrolled a total of 64 healthy subjects including 5 intravenous cohorts and 3 subcutaneous cohorts.

The SAD Study data of LAE102 demonstrated an encouraging safety and tolerability profile, with no serious adverse events and no discontinuations due to adverse events. All treatment emergent adverse events reported to date were very well tolerated, with the majority of them being reported as mild (grade 1) lab test abnormality without any clinical symptoms or signs. There is no reported case of diarrhea. Obvious target engagements and expected pharmacodynamic biomarker changes have been observed. Single doses of LAE102 resulted in significant and sustained increase in activin A level, indicating a robust target engagement. The duration of target engagement correlated to the dose level. The detailed study results will be presented at an international scientific conference in 2025. The positive outcomes of the SAD Study results have established a solid foundation for the Phase I MAD Study.

The Group targets to commence the Phase I MAD Study in China in March 2025. The Phase I MAD Study is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of LAE102, administered subcutaneously, in 60 overweight/obese subjects. The Group aims to bring this precision therapy to overweight and obese patients who are in need of novel treatment options for achieving quality weight control.

Laekna team has accumulated tremendous experience and extensive knowhow in this specific field and is developing, in addition to LAE102, more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor against ActRIIA/IIB. Both are our internally discovered antibodies for muscle and other disease indications. IND-enabling studies of both antibodies have been initiated in 2024. We target to submit IND applications for LAE103 and LAE123 in the second quarter and the fourth quarter of 2025 respectively.

LAE002 (afuresertib)

LAE002 (afuresertib) is an adenosine triphosphate (ATP) competitive AKT inhibitor. We in-licensed LAE002 (afuresertib) from Novartis in 2018. Prior to our in-licensing, 11 clinical trials had been conducted to demonstrate the safety and efficacy profiles of LAE002(afuresertib) by Novartis and GSK.

LAE002 (afuresertib) + Fulvestrant in HR+/HER2-breast cancer, Phase III

According to Frost & Sullivan, the global and China's incidence of breast cancer is expected to increase from 2,301.2 thousand and 336.3 thousand in 2021 to 2,666.4 thousand and 372.4 thousand in 2030, respectively. It is estimated that more than 60% of patients with breast cancer have HR+/HER2- molecular signature in China. The endocrine/anti-estrogen therapies in combination with CDK4/6 inhibitors have emerged as the first- and/or the second-line treatment for patients with HR+/HER2- breast cancer. However, 15% to 20% of patients are intrinsically resistant to the treatment, and another 30% to 40% patients will develop acquired resistance to the treatment over time. HR+/HER2-breast cancer post CDK4/6 inhibitors and endocrine treatments remain as a huge unmet medical need and represent a multi-billion dollar market potential.

We have initiated a Phase Ib trial in China and the U.S. for the treatment of HR+/HER2-LA/mBC with LAE002 (afuresertib), in a combination of a SOC treatment fulvestrant. The results of our Phase Ib study in this combination therapy have shown promising anti-cancer efficacy with a well-tolerated safety profile. The data of this study have been presented during a poster spotlight session at the 2023 San Antonio Breast Cancer Symposium (SABCS) in December 2023. The Group also presented the updated clinical data of all enrolled subjects and the subjects with positive biomarker in this Phase Ib study as a poster presentation at the European Society for Medical Oncology (ESMO) Congress in Barcelona, Spain in September 2024.

As of the data cut-off date of August 27, 2024, results of the Phase Ib study in all 31 subjects and in a subgroup with PIK3CA/AKT1/PTEN alterations from the U.S. and China have demonstrated promising anti-cancer efficacy with a well-tolerated safety profile. Among the 18 subjects with PIK3CA/AKT1/PTEN-alterations, the confirmed objective response rate was 33.3%, the clinical benefit rate was 66.7%, and the median PFS was 7.3 months.

The Group commenced the Phase III Clinical Trial AFFIRM-205 in China for LAE002 (afuresertib, an oral AKT inhibitor) plus fulvestrant in patients with PIK3CA/AKT1/PTEN alterations and HR+/HER2-LA/mBC in May 2024. The Phase III Clinical Trial AFFIRM-205 is a multi-center, randomized, double-blind, placebo-controlled pivotal study to further assess the anti-tumor efficacy and safety of the combination therapy. Study recruitment is on track. The Group targets to complete subject enrollment in the fourth quarter of 2025 and to submit NDA to CDE in the first half of 2026.

LAE002 (afuresertib) +LAE001/prednisone in mCRPC, Phase II

According to Frost & Sullivan, the global and China's incidence of prostate cancer is expected to increase from 1,451.5 thousand and 120.9 thousand in 2021 to 1,815.1 thousand and 199.3 thousand in 2030, respectively. Patients with prostate cancer that have relapsed after local therapy or that have distant metastasis usually respond to androgen deprivation therapy (ADT). However, despite receiving ADT, most of these patients eventually experience disease progression and develop castration-resistant prostate cancer (CRPC).

We initiated a Phase II multi-regional clinical trial of the study of LAE201 in patients with mCRPC following SOC treatment in the U.S. in June 2021, and South Korea in September 2022. The trial is an open-label, dose-escalation and dose expansion study to assess the efficacy and safety of the combination candidate. The study demonstrated promising treatment benefit for mCRPC patients. As of November 21, 2023, 40 subjects who progressed on 1-3 lines of standard treatments, including at least 1 line of abiraterone, or the second generation of AR antagonists, had been enrolled in the recommended Phase II dose group. The median rPFS was 8.1 months. This is a significant improvement compared to the median rPFS of 2 to 4 months of mCRPC patients under the standard treatments historically. The combination therapy was generally tolerable with manageable treatment emergent adverse events and recoverable after routine treatments.

Design of the Phase III pivotal trial of LAE201 in patients with mCRPC following SOC treatment has been discussed with FDA. In May 2024, the Group obtained approval from FDA for the protocol of this Phase III clinical trial. We plan to pursue strategic partnerships to accelerate the development and commercialization of LAE002 (afuresertib) and LAE001 to address the great unmet medical need for cancer therapies.

LAE002 (afuresertib) +Paclitaxel for PROC (PROFECTA-II), Phase II

PROC is broadly defined as ovarian cancer recurrence within six months of completing platinum-based chemotherapy, either in the primary or recurrent setting. PROC is generally associated with low response rates to standard chemotherapy with the ORR of 10% to 15%, and median PFS of 3.5 months only, indicating limited effective treatment options and poor prognosis. Treatment options are limited for PROC. According to Frost & Sullivan, the global and China's incidence of ovarian cancer is expected to increase from 319.8 thousand and 56.2 thousand in 2021 to 374.2 thousand and 62.7 thousand in 2030, respectively.

We have initiated a global MRCT Phase II trial (PROFECTA-II) in both the U.S. and China to treat PROC patients with LAE002 (afuresertib) plus paclitaxel. It was a Phase II, randomized, open-label, active-controlled study evaluating the efficacy and safety of LAE002 (afuresertib) in combination with paclitaxel versus paclitaxel in 150 subjects with PROC. In January 2024, we had achieved database lock and announced the top-line data. The study showed reduced risk of disease progression or death (progression-free survival; PFS) with a HR of 0.744 (95% CI: 0.502–1.102) but missed statistical significance. For biomarker subgroup with phospho-AKT positive, IHC>1, (37%), the study data demonstrated that LAE002 (afuresertib) combination arm significantly improved PFS, and the median PFS is 5.4m vs 2.9m with HR of 0.352 (95% CI: 0.125–0.997). The trial has shown a manageable and tolerable safety profile and adverse events were consistent with the known safety profiles of the individual treatments. We plan to pursue strategic partnerships to support further development of this program.

In addition, we are actively conducting other clinical trials to further expand the indications of LAE002 (afuresertib) in other cancers. A Phase I study of a combination therapy with sintilimab targeting patients with solid tumors progressed upon prior PD-1/PD-L1 treatments and/or chemotherapy was completed in 2024. We have observed high response rate in cervical and endometrial cancer patients who have been treated up to 3 lines of SOCs, including PD-1 drugs and/or chemotherapy. We presented the data of this LAE002 (afuresertib)+Sintilimab+nab-paclitaxel Phase I clinical trial at the 2024 annual global meeting of the International Gynecologic Cancer Society (“IGCS”) in Dublin, Ireland in October 2024.

LAE001

LAE001 is an androgen synthesis inhibitor that inhibits both CYP17A1 and CYP11B2. We in-licensed LAE001 from Novartis in 2017. According to Frost & Sullivan, LAE001 is the only dual CYP17A1/CYP11B2 inhibitor in clinical trials for the treatment of prostate cancer globally. As a dual CYP17A1/CYP11B2 inhibitor, LAE001 can block both androgen and aldosterone synthesis and potentially be administered without prednisone, the short-term high dose or long-term exposure of which can lead to a variety of adverse events.

We completed a Phase I clinical trial of LAE001 as a monotherapy and a Phase II clinical trial of LAE001 plus LAE002 (afuresertib) in patients with mCRPC to assess the safety and efficacy of the therapies. Design of the Phase III pivotal trial of LAE201 in patients with mCRPC following SOC treatment has been discussed with FDA and approval of the same was obtained in May 2024. We plan to pursue strategic partnerships to accelerate the development and commercialization of LAE001 to address the unmet medical need for cancer therapies.

LAE005

LAE005 is a high-affinity, ligand-blocking, humanized anti-PD-L1 IgG4 antibody. In pre-clinical and clinical studies, LAE005 demonstrated its strong binding avidity to PD-L1 and compelling anti-tumor activities. Specifically, we are evaluating the therapeutic potential of the combination therapy of LAE002 (afuresertib) and LAE005 in patients with TNBC. We believe LAE005 has the potential to serve as an effective therapy for the treatment of TNBC when combined with other synergistic mechanisms.

The results of our Phase I clinical trial of LAE002 (afuresertib) in combination with LAE005 (anti-PDL1 mAb) plus nab-paclitaxel for the treatment of triple-negative breast cancer (TNBC) were presented at the 2024 Annual Meeting of the American Association for Cancer Research (AACR) in April 2024. A total of 22 subjects with advanced solid tumors were enrolled and dosed in this Phase I study, among which there were 14 TNBC subjects who completed at least 2 cycles of treatment and had at least 1 tumor assessment. The median value of previous treatment lines of these 14 subjects was 1.5 (0-3). Among them, five showed confirmed partial response (ORR 35.7%), four had stable disease (28.6%), resulting in a disease control rate (DCR) of 64.3% in the best response assessment. The median duration of response (DOR) was 9.26 months. Five TNBC subjects were treated for more than 32 weeks, with one subject reaching a duration of 73 weeks. This case study has been selected for the “Chinese Clinical Case Achievement Database” (with the PFS of this case being 16 months as of September 28, 2023).

CAUTIONARY STATEMENT: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP OR MARKET THE RELEVANT PRODUCTS, OR ANY OF OUR PIPELINE PRODUCTS, SUCCESSFULLY.

FINANCIAL REVIEW

The following discussion is based on, and should be read in conjunction with, the financial information and notes included elsewhere in this announcement.

Other Income

Our other income increased by RMB21.5 million or 128.7% from RMB16.7 million in 2023 to RMB38.2 million in 2024, which was primarily attributable to the increase in interest income from bank deposits in 2024.

Other Losses

Our other losses decreased by RMB6.0 million or 95.2% from RMB6.3 million in 2023 to RMB0.3 million in 2024, which was primarily attributable to the decrease in net foreign exchange losses.

Administrative Expenses

Our administrative expenses decreased by RMB1.8 million or 2.4% from RMB75.9 million in 2023 to RMB74.1 million in 2024. Such decrease was primarily attributable to the fact that, during the Reporting Period, the Group did not record any listing expenses as the Company's shares were successfully listed on the Main Board of the Stock Exchange in June 2023 and the listing expenses were fully recorded by the end of 2023.

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Staff costs	56,043	46,136
Professional service expenses	12,250	10,084
Listing expenses	–	12,953
Others	5,765	6,705
Total	74,058	75,878

Research and Development Expenses

Our research and development expenses decreased by RMB15.4 million or 6.7% from RMB230.5 million in 2023 to RMB215.1 million in 2024, which was primarily attributable to (i) the decrease in clinical development expenses from RMB108.3 million in 2023 to RMB78.6 million in 2024 as the Group mainly focused on the prioritized clinical programs during the year ended December 31, 2024, and which was partially offset by (ii) the increase in clinical trial milestone payment from nil in 2023 to RMB17.8 million in 2024, which was related to Phase III Clinical Trial AFFIRM-205 as first patient enrolled in May 2024.

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Staff costs	78,679	87,564
Discovery research expenses	27,948	25,258
Clinical development expenses	78,633	108,335
Clinical trial milestone payment	17,785	–
Others	12,070	9,328
Total	215,115	230,485

Fair Value Changes on Financial Instruments Issued to Investors

Our fair value changes on financial instruments issued to investors decreased from RMB71.2 million in 2023 to nil in 2024. Fair value changes on financial instruments issued to investors were related to preferred shares. All preferred shares were converted into ordinary shares of the Company upon the completion of the Listing. Thus, no such losses were incurred during the Reporting Period.

Liquidity and Financial Resource

As of December 31, 2024, the current assets of the Group were RMB813.4 million, including cash and cash equivalents of RMB636.4 million, time deposits with an original maturity over three months of RMB163.6 million and other current assets of RMB13.4 million. Among them, the Group's cash and cash equivalents increased by RMB195.6 million or 44.4% to RMB636.4 million as of December 31, 2024 from RMB440.8 million as of December 31, 2023. The Group's time deposits decreased by RMB174.5 million or 51.6% to RMB163.6 million as of December 31, 2024 from RMB338.1 million as of December 31, 2023. As of December 31, 2024, the current liabilities of the Group were RMB148.5 million, including other payables of RMB47.5 million, interest-bearing bank loans of RMB99.0 million and current lease liabilities of RMB2.0 million.

Our cash and bank balances (including cash and cash equivalents and time deposits) as of December 31, 2024, were RMB800.0 million, of which RMB35.3 million, RMB759.7 million and RMB5.0 million were denominated in RMB, USD, and HKD, respectively representing an increase of 2.7% as compared to the cash and bank balances (including cash and cash equivalents and time deposits) of RMB778.9 million as of December 31, 2023. The increase was primarily attributable to the proceeds from the Placing in November 2024.

Funding and Treasury Policy

The Group adopts a prudent funding and treasury policy, aiming to maintain an optimal financial position and minimal financial risks. We have formulated internal control measures to control our process of investment in wealth management products. Prior to making an investment, we ensure that there remains sufficient working capital for our operations, R&D activities and capital expenditures. In 2024, we funded our operations primarily through equity financing and bank loans. With the continuing expansion of our business and development of new drug candidates, we will use the net proceeds raised from the Global Offering and the Placing and may require further funding through public or private equity offerings, debt financing and other sources.

Bank Loans

Our bank loans as of December 31, 2024 were RMB99.0 million (December 31, 2023: RMB49.4 million), all of which were denominated in RMB and carried fixed nominal interest rates ranging from 3.20% to 4.10% per annum.

Current ratio

Current ratio (calculated by current assets divided by current liabilities) of the Group as of December 31, 2024, was 5.48 (December 31, 2023: 6.58).

Gearing ratio

Gearing ratio is calculated by using interest-bearing borrowings and lease liabilities less cash and cash equivalents, divided by total equity and multiplied by 100%. As of December 31, 2024, the Group was in a net cash position and thus, gearing ratio is not applicable.

Foreign Currency Risk

We have transactional currency exposures. Certain of our cash and bank balances, time deposits, prepayments, other receivables and other payables are denominated in non-functional currencies and 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.

Contingent Liabilities

As of December 31, 2024, we did not have any material contingent liabilities.

Significant Investments Held

As of December 31, 2024, the Group did not hold any significant investments. Save as disclosed in this announcement, as of December 31, 2024, the Group did not have future plans for material investments and investment in capital assets.

Pledge of Assets

As of December 31, 2024, we did not pledge any of our assets.

Employees and Remuneration Policies

As of December 31, 2024, the Group had 86 employees. The total employee benefit expenses for 2024, including share-based payment expenses, were RMB134.7 million, as compared to RMB133.7 million for 2023.

Our employees' remuneration comprises salaries, bonuses, provident funds, social security contributions and other welfare payments. We have made contributions to our employees' social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations.

We adopted the Post-IPO Share Option Scheme on June 9, 2023, which was immediately prior to Listing. We further adopted the 2024 Share Award Scheme on June 14, 2024. Each of the schemes constitutes a share scheme governed by Chapter 17 of the Listing Rules.

Material Acquisitions and Disposals

During the Reporting Period, the Group did not have any material acquisition or disposal of its subsidiaries, associates and joint ventures.

Use of Net Proceeds from the Global Offering

On June 29, 2023, 63,728,000 shares of US\$0.00001 each were issued at a price of HK\$12.41 per share in connection with the Company's listing on the Main Board of the Stock Exchange. The net proceeds of HK\$724.4 million from the Global Offering were used during the Reporting Period, and the unutilized net proceeds are intended to be used, in accordance with the intended use of proceeds as previously set out in the Prospectus.

The below table sets out the proposed and actual applications of the net proceeds from the Listing Date to December 31, 2024:

Intended use of Net Proceeds	Net Proceeds from the Global Offering (HK\$ million)	Approximate % of total Net Proceeds	Utilized Net		Utilized Net Proceeds from the Global Offering as of December 31, 2024 (HK\$ million)	Unutilized Net Proceeds from the Global Offering as of December 31, 2024 (HK\$ million)	Expected timeline of full utilization of the unutilized Net Proceeds ⁽¹⁾
			Unutilized Net Proceeds from the Global Offering as of January 1, 2024 (HK\$ million)	Proceeds from the Global Offering during the year ended December 31, 2024 (HK\$ million)			
For rapidly advancing the clinical development and approval of our Core Products, i.e. LAE001 and LAE002 (afuresertib)	407.8	56.3%	337.6	156.6	226.8	181.0	Before December 31, 2026
For accelerating the research and development of other existing pipeline products and continuously advancing and improving our pipeline products	150.7	20.8%	119.6	84.0	115.1	35.6	Before December 31, 2025
For improving our production capabilities and developing our manufacturing capacities	71.7	9.9%	71.2	4.4	4.9	66.8	Before December 31, 2027
For business development activities and enhancing our global reach	55.1	7.6%	48.3	13.6	20.4	34.7	Before December 31, 2027
For working capital and other general corporate purposes	39.1	5.4%	14.6	14.6	39.1	–	

Note:

- (1) The expected timeline is based on the best estimation made by the Group on future market condition and may change with the future market condition and future development. Given the challenging macroeconomic environment, the Group has strived to maintain a strict financial discipline, which we believe is essential for the Group's success. Thus, the expected timeline of full utilization of the unutilized net proceeds from the Global Offering were delayed compared to the timeline disclosed in the interim report of the Company dated August 16, 2024 for the six months ended June 30, 2024 as a result of the more prudent spending control approach we have implemented based on our actual business needs and development. The Group will continue to implement disciplined development strategy to ensure our healthy financial position and stable cash flow position.

Use of Net Proceeds from the Placing

On November 27, 2024, the Company completed a placing of an aggregate of 17,636,000 Placing Shares by the Sole Placing Agent to not less than six Placees at a price of HK\$13.36 per Placing Share pursuant to the terms and conditions of the Placing Agreement. The gross proceeds from the Placing were approximately HK\$235.6 million. The Company received net proceeds from the Placing, after deducting the placing commission and other related expenses and professional fees, of approximately HK\$230.4 million. The net proceeds from the Placing were used during the Reporting Period, and the unutilized net proceeds are intended to be used, in accordance with the intended use of proceeds as previously set out in the announcement of the Company dated November 21, 2024.

The below table sets out the proposed and actual applications of the net proceeds during the Reporting Period:

	Net Proceeds from the Placing (HK\$ million)	Approximate % of total Net Proceeds	Utilized Net Proceeds from the Placing as of December 31, 2024 (HK\$ million)	Unutilized Net Proceeds from the Placing as of December 31, 2024 (HK\$ million)	Expected timeline of full utilization of the unutilized Net Proceeds ⁽¹⁾
Intended use of Net Proceeds					
For accelerating research and development of LAE102 and other drug assets targeting ActRII receptors	230.4	100%	2.1	228.3	Before December 31, 2026

Note:

- (1) The expected timeline is based on the best estimation made by the Group on future market condition and may change with the future market condition and future development.

FUTURE DEVELOPMENT

We will continue to advance and expand our product portfolio in the therapeutic areas where we have accumulated tremendous experience and extensive know-how.

LAE102 is our internally discovered monoclonal antibody against ActRIIA. Blocking Activin-ActRII pathway could promote skeletal muscle regeneration and decrease fat mass, and this positions LAE102 as a promising drug candidate for achieving quality weight control. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor against ActRIIA/IIB. Both are our internally discovered antibodies for muscle and other disease indications. The Group has established a comprehensive ActRII portfolio and strives to maximize the value of targeting ActRII receptors.

We are in the process of developing multiple innovative drug candidates, including small molecules, bispecific antibodies, and bifunctional NK engagers against various diseases. We aim to advance our pipeline to address the unmet medical need of underserved patients and target to have one drug candidate entering the clinical stage each year.

The Group also actively explores potential combination therapy opportunities among our pipeline and with existing approved drugs as well as conventional therapies. Our LAE002 (afuresertib) combination trial with Fulvestrant has demonstrated remarkable clinical value to treat HR+/HER2- breast cancer patients who have failed previous standard of care treatments of endocrine/anti-estrogen therapies, including CDK4/6 inhibitors which represent a big unmet medical need with huge market potential. Our combination therapy of LAE002 (afuresertib) plus LAE001 to treat the second-generation A/AR drug-resistant mCRPC also demonstrated promising treatment benefits to mCRPC patients. We are committed to unleashing the clinical values of our drug candidates.

During the Reporting Period, the Group has entered into a clinical collaboration agreement with Lilly to support and accelerate global clinical development of LAE102 for the treatment of obesity. We plan to pursue more strategic partnerships with global leading pharmaceutical companies to accelerate clinical development and commercialization of our drug candidate assets. We keep advancing and expanding our pipeline and are committed to bringing life-changing medicines to more people around the world.

CORPORATE GOVERNANCE RELATED INFORMATION

Compliance with Corporate Governance Code

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted the CG Code contained in Appendix C1 to the Listing Rules as its own code of corporate governance. The Directors are of the view that during the Reporting Period and up to the date of this announcement, the Company has complied with all applicable code provisions of the CG Code save and except for the following deviation from code provision C.2.1 of the CG Code.

Under code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Dr. LU Chris Xiangyang (“**Dr. Lu**”) has served as our chairman since May 2018 and Chief Executive Officer since April 2017. Dr. Lu is the founder of our Group and has extensive experience in the business operations and management of our Group. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned, Dr. Lu is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our Chief Executive Officer. Our Board also believes that the combined role of chairman and chief executive officer can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Directors consider that the balance of power and authority will not be impaired due to this arrangement. In addition, all major decisions are made in consultation with members of the Board, including the relevant Board committees, and three independent non-executive Directors.

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 chairman and the chief executive officer is necessary.

Compliance with the Model Code for Securities Transactions

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors and the Company’s senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Company or its securities.

Upon specific enquiry, all Directors confirmed that they have complied with the Model Code during the Reporting Period and up to the date of this announcement. In addition, the Company is not aware of any non-compliance of the Model Code by the employees of the Company who are likely to be in possession of inside information of the Company during the Reporting Period and up to the date of this announcement.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

On November 27, 2024, the Company completed a placing of an aggregate of 17,636,000 Placing Shares by the Sole Placing Agent to not less than six Placees at a price of HK\$13.36 per Placing Share pursuant to the terms and conditions of the Placing Agreement, representing approximately 4.33% of the issued share capital of the Company as enlarged by the allotment and issue of the Placing Shares immediately upon completion of the Placing.

The placing price of HK\$13.36 per Placing Share was determined after arm's length negotiations between the Company and the Sole Placing Agent and represents (i) a discount of approximately 15.01% to the closing price of HK\$15.72 per Share as quoted on the Stock Exchange on November 20, 2024, being the trading day immediately preceding the date of the Placing Agreement and (ii) a premium of approximately 12.84% to the average closing price of HK\$11.84 per Share as quoted on the Stock Exchange for the five consecutive trading days of the Shares immediately preceding the date of the Placing Agreement.

The gross proceeds from the Placing were approximately HK\$235.6 million. The Company received net proceeds from the Placing, after deducting the placing commission and other related expenses and professional fees, of approximately HK\$230.4 million.

Further details of the Placing and the use of proceeds are set out in the announcements of the Company dated November 21, 2024 and November 27, 2024, respectively.

Save as disclosed above, neither the Company nor any of its subsidiaries purchased, redeemed or sold any of the Company's listed securities (including sale of treasury shares (as defined under the Listing Rules)) during the Reporting Period. As of December 31, 2024, the Company did not hold any treasury shares (as defined under the Listing Rules).

AUDIT COMMITTEE AND REVIEW OF ANNUAL RESULTS

The Company has established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the CG Code. The primary duties of the Audit Committee are to assist the Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of the Group, overseeing the audit process and performing other duties and responsibilities as assigned by the Board. The Audit Committee currently consists of two independent non-executive Directors being Mr. ZHOU Jian and Dr. LI Min, and one non-executive Director being Dr. WANG David Guowei. The chairperson of the Audit Committee is Mr. ZHOU Jian. Mr. ZHOU Jian holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules.

The Audit Committee had reviewed, together with the management, the accounting principles and policies adopted by the Group and discussed internal controls and financial reporting matters including a review of the consolidated financial statements and annual results of the Group for the year ended December 31, 2024.

SCOPE OF WORK OF AUDITOR

The financial figures in respect of the Group's consolidated statement of profit or loss and other comprehensive income, consolidated statement of financial position and the related notes thereto for the year ended December 31, 2024 as set out in this announcement have been agreed by the Group's auditor, KPMG, Certified Public Accountants, to the amounts set out in the Group's consolidated financial statements for the year ended December 31, 2024. The work performed by KPMG in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by KPMG on this announcement.

EVENTS AFTER THE REPORTING PERIOD

Save as disclosed in this announcement and as at the date of this announcement, there were no material subsequent events after the Reporting Period.

FINAL DIVIDEND

The Board does not declare the payment of a final dividend to the Shareholders for the Reporting Period.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement is published on the website of the Stock Exchange at www.hkexnews.hk and on the website of the Company at www.laekna.com. The annual report of the Company for the year ended December 31, 2024 containing all the information required by the Listing Rules will be published on the same websites and despatched (if requested) to the Shareholders in due course.

DEFINITIONS

In this announcement, unless the context otherwise requires, the following expressions shall have the following respective meanings:

“AE”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“AKT”	a serine/threonine protein kinase with 3 isoforms (AKT1, AKT2 and AKT3) that participate in multiple pathways regulating several cellular processes, including survival, proliferation, tissue invasion, and metabolism
“Audit Committee”	the audit committee of the Board
“Board”	the board of directors of our Company
“CDE”	the center for drug evaluation of the NMPA
“CG Code”	the Corporate Governance Code as set out in Appendix C1 to the Listing Rules
“China” or “PRC”	the People’s Republic of China, but for the purpose of this announcement and for geographical reference only and except where the context requires otherwise, references in this announcement to “China” and the “PRC” do not apply to Hong Kong Special Administrative Region of the People’s Republic of China, Macau Special Administrative Region of the People’s Republic of China and Taiwan, Province of China
“Company” or “our Company”	Laekna, Inc. (來凱醫藥有限公司), an exempted company incorporated in the Cayman Islands with limited liability on July 29, 2016
“Director(s)” or “our Director(s)”	the directors of the Company

“FDA”	the United States Food and Drug Administration
“Global Offering”	the Hong Kong Public Offering and the International Offering
“Group”, “our Group”, “we” or “our”	our Company and its subsidiaries
“HK\$” or “HKD”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“Hong Kong”	the Hong Kong Special Administrative Region of the People’s Republic of China
“HR+/HER2-breast cancer”	the most common type of breast cancer with overexpression of HR and without overexpression of HER2
“IHC”	immunohistochemistry, a test that uses a chemical dye to stain and measure specific proteins
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials; also known as clinical trial application, or CTA, in China
“Listing”	the listing of the Shares on the Main Board of the Stock Exchange
“Listing Date”	June 29, 2023
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended or supplemented from time to time
“mCRPC”	metastatic castration resistant prostate cancer
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules

“MRCT”	multi-regional clinical trials
“NDA”	new drug application
“NMPA”	the 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)
“Novartis”	Novartis Pharma AG, a company organized under the laws of Switzerland and one of our Pre-IPO Investors
“PCC”	pre-clinical candidate
“PD-1”	programmed cell death protein 1
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works
“Placee(s)”	any individuals, corporate, institutional or other investor(s) procured by the Sole Placing Agent or their respective agents to subscribe for any of the Placing Shares pursuant to the Placing Agreement
“Placing”	the placing of 17,636,000 Placing Shares pursuant to the terms of the Placing Agreement
“Placing Agreement”	the conditional placing agreement entered into between the Company and the Sole Placing Agent dated November 21, 2024 in relation to the Placing
“Placing Shares”	17,636,000 shares placed pursuant to the Placing Agreement
“PROC”	platinum resistant ovarian cancer
“Prospectus”	the prospectus of the Company dated June 16, 2023

“Reporting Period”	year ended December 31, 2024
“RMB”	Renminbi, the lawful currency of China
“rPFS”	radiographic progression free survival
“SAE”	serious AE, any medical occurrence in human drug trials that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage
“Share(s)”	ordinary share(s) in the share capital of our Company with a par value of US\$0.00001 each
“Shareholder(s)”	holder(s) of Shares
“SOC”	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“Sole Placing Agent”	CLSA Limited, being the sole placing agent and sole overall coordinator of the Placing
“South Korea”	the Republic of Korea
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“TEAE”	adverse events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
“TNBC”	triple-negative breast cancer, any breast cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2
“treasury shares”	has the meaning as defined under the Listing Rules
“United States”, “USA” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction

“US\$” or “USD” United States dollars, the lawful currency of the United States

“%” per cent

By Order of the Board
Laekna, Inc.
Dr. LU Chris Xiangyang
Chairman

Hong Kong, March 24, 2025

As at the date of this announcement, the Board comprises Dr. LU Chris Xiangyang, Ms. XIE Ling and Dr. GU Xiang-Ju Justin as executive Directors; Dr. WANG David Guowei and Mr. SUN Yuan as non-executive Directors; and Dr. YIN Xudong, Dr. LI Min and Mr. ZHOU Jian as independent non-executive Directors.