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, 2023

The Board of Laekna, Inc. is pleased to announce the consolidated annual results of the Group for the year ended December 31, 2023, together with comparative figures for the year ended December 31, 2022, 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 our clinical and pre-clinical candidate development and expansion of our product pipeline. For the year ended December 31, 2023, we made the following milestones and achievements:

Advancing the Clinical Trials

Afuresertib +Fulvestrant in HR+/HER2-breast cancer, Phase Ib/III

The preliminary data from the combination therapy of afuresertib plus fulvestrant has shown promising anti-cancer efficacy with a well-tolerated safety profile in patients with HR+/HER2- locally advanced or metastatic breast cancer (LA/mBC) who had disease progression after 1–2 prior lines of standard of care therapies. The results of a Phase Ib study with 20 subjects from U.S. and China were presented during a poster spotlight session at the 2023 San Antonio Breast Cancer Symposium (SABCS) in December 2023. Currently, the Phase III pivotal trial of afuresertib plus fulvestrant in patients with HR+/HER2- LA/mBC has been initiated.

Afuresertib +LAE001/prednisone in mCRPC, Phase II

We initiated a Phase II clinical trial of the MRCT study of LAE001 and prednisone plus Afuresertib in patients with mCRPC following SOC treatment in the U.S. in June 2021, and South Korea in September 2022. We completed the patient enrollment in March 2023. The study demonstrated promising treatment benefit for mCRPC patients. The detailed study readouts including efficacy and safety data was presented in the European Society for Medical Oncology (ESMO) Congress in October 2023. A following Phase III pivotal trial design is under discussion with regulatory agencies.

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

150 patients have been fully enrolled and database lock was achieved in December 2023. Top-line data of the global MRCT Phase II registrational trial (PROFECTA-II) in both U.S. and China to treat Platinum-Resistant Ovarian Cancer (PROC) patients with afuresertib plus paclitaxel 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%), study data demonstrated that 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 will discuss the results with regulatory authorities to identify a registration path for PROC patient populations that may benefit from afuresertib.

LAE102 IND approval

LAE102 is our internally discovered monoclonal antibody against ActRIIA. We have obtained the IND approval from FDA and CDE in May 2023 and in the first quarter of 2024 respectively in cancer indications. Besides of cancer indications, we will also explore LAE102 in obesity indication. We submitted IND applications to CDE and FDA respectively for LAE102 in relation to obesity indication in the first quarter of 2024. And we plan to commence clinical trial process after obtaining IND approval and is committed to bring this precision therapy to obesity patients who are in needs of the novel treatment options. Blocking Activin-ActRII pathway could promote skeletal muscle regeneration and decrease fat mass. Laekna team has accumulated tremendous experiences and deep knowhow in this specific field and are developing more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor for ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle regeneration and other disease indications in the drug candidate pipeline.

Pre-clinical candidates (PCC) declaration

For the year ended December 31, 2023, we have advanced seven PCC drug candidates from our internal discovery platform: LAE103, monoclonal antibody against ActRIIB for indications related to muscle regeneration; LAE105, a bi-functional aHSC-NK engager with sHSC killing and anti-fibrosis activity; LAE111, a LILRB1 and LILRB2 bispecific antibody; LAE112, a FGFR2b monoclonal antibody; LAE113, a TIGIT-PVRIG bispecific antibody; LAE119, a PARP1-selective inhibitor; and LAE120, an USP1 inhibitor. IND-enabling studies have been initiated for LAE120.

Expected Upcoming Milestones

- Obtaining IND approval of LAE102 obesity indication from CDE and FDA in the second quarter of 2024;
- Initiating first-in-human clinical study of LAE102 in the second half of 2024;
- Initiating patient recruitment of Afuresertib+fulvestrant Phase III clinical study in the second half of 2024;
- IND submission for LAE120 in the fourth quarter of 2024;
- Presenting Afuresertib+LAE005+nab-paclitaxel Phase I clinical study results as a poster presentation at American Association for Cancer Research annual meeting in April 2024 (AACR 2024);
- Presenting LAE119/PARP1-selective inhibitor and LAE120/USP1 inhibitor as a poster presentation at American Association for Cancer Research annual meeting in April 2024 (AACR 2024);
- Plan to present Afuresertib+Sintilimab+nab-paclitaxel Phase I clinical study results in a scientific conference in the second half of 2024; and
- Plan to present more Afuresertib+fulvestrant Phase Ib clinical data and biomarker data in a scientific conference in second half of 2024.

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Research and development expenses	**230,485**	313,356
Administrative expenses	**75,878**	80,238
Fair value changes on financial instruments issued to investors	**71,210**	387,056
Loss for the year	**368,814**	781,594
Total comprehensive loss for the year	**458,674**	902,197

Our research and development expenses decreased by RMB82.9 million or 26.4% from RMB313.4 million in 2022 to RMB230.5 million in 2023. Such decrease was primarily attributable to (i) decreased discovery research expenses as a result of the pre-clinical candidate LAE102 obtaining IND approval in early 2023, and (ii) decreased clinical development expenses primarily attributable to the decreased CMC-related service expenses.

Our administrative expenses decreased by RMB4.3 million or 5.4% from RMB80.2 million in 2022 to RMB75.9 million in 2023. Such decrease was primarily attributable to the decrease in listing expenses.

Fair value changes on financial instruments issued to investors were related to preferred shares and warrant. All preferred shares were converted into ordinary shares of the Company upon completion of the Listing, and the warrant was exercised on March 31, 2022.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended December 31, 2023
(Expressed in Renminbi)

	Note	**2023** ***RMB'000***	2022 *RMB'000*
Other income	*4*	**16,742**	4,798
Other losses		**(6,256)**	(4,353)
Administrative expenses		**(75,878)**	(80,238)
Research and development expenses		**(230,485)**	(313,356)
Loss from operations		**(295,877)**	(393,149)
Finance costs	*5(a)*	**(1,727)**	(1,389)
Fair value changes on financial instruments issued to investors		**(71,210)**	(387,056)
Loss before taxation	*5*	**(368,814)**	(781,594)
Income tax	*6*	**–**	–
Loss for the year		**(368,814)**	(781,594)
Other comprehensive income for the year (after tax and reclassification adjustments)			
Item that will not be reclassified to profit or loss:			
Exchange differences on translation of financial statements of the Company		**(79,050)**	(71,656)
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of financial statements of foreign subsidiaries		**(10,810)**	(48,947)
Total comprehensive income for the year		**(458,674)**	(902,197)
Loss per share			
Basic and diluted *(RMB)*	*7*	**(1.68)**	(10.19)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As of December 31, 2023
(Expressed in Renminbi)

	Note	**2023** ***RMB'000***	2022 *RMB'000*
Non-current assets			
Property, plant and equipment		**4,506**	5,273
Intangible assets	*8*	**124,229**	123,631
Right-of-use assets		**6,510**	8,246
Other non-current assets		**9,009**	8,083
		144,254	145,233
Current assets			
Prepayments and other receivables		**9,114**	11,561
Time deposits	*9*	**338,120**	–
Cash and cash equivalents	*10*	**440,815**	323,070
		788,049	334,631
Current liabilities			
Bank loans	*11*	**49,400**	19,782
Other payables	*12*	**68,445**	75,868
Lease liabilities		**1,917**	1,859
		119,762	97,509
Net current assets		**668,287**	237,122
Total assets less current liabilities		**812,541**	382,355
Non-current liabilities			
Lease liabilities		**5,069**	6,660
Deferred income		**3,500**	3,500
Financial instruments issued to investors	*13*	**–**	2,277,281
		8,569	2,287,441
NET ASSETS/(LIABILITIES)		**803,972**	(1,905,086)
CAPITAL AND RESERVES			
Share capital		**27**	5
Treasury shares		**(2)**	–
Reserves		**803,947**	(1,905,091)
TOTAL EQUITY/(DEFICIT)		**803,972**	(1,905,086)

CONSOLIDATED CASH FLOW STATEMENT

For the year ended December 31, 2023
(Expressed in Renminbi)

	Note	**2023** ***RMB'000***	2022 *RMB'000*
Operating activities			
Cash used in operations		**(295,603)**	(306,283)
Net cash used in operating activities		**(295,603)**	(306,283)
Investing activities			
Payment for purchase of property, plant and equipment		**(864)**	(2,983)
Payment for purchase of intangible assets		**(449)**	(2,102)
Increase in time deposits with original maturity over three months		**(338,120)**	–
Interest received from bank deposits	*4*	**13,988**	823
Payment for purchase of wealth management products		**(150,280)**	(22,847)
Proceeds from redemption of wealth management products		**152,564**	22,889
Net cash used in investing activities		**(323,161)**	(4,220)
Financing activities			
Proceeds from bank loans		**54,400**	19,650
Repayment of bank loans		**(24,960)**	(2,000)
Interest paid for bank loans		**(1,359)**	(173)
Proceeds from issuance of preferred shares		**–**	301,028
Proceeds from shares issued under share option scheme		**–**	54
Proceeds from issuance of ordinary shares through initial public offering, net of issuance costs		**709,794**	(5,029)
Payment for capital element of lease liabilities		**(1,533)**	(511)
Payment for interest element of lease liabilities		**(368)**	(439)
Net cash generated from financing activities		**735,974**	312,580

	2023	2022
	RMB'000	*RMB'000*
Net increase in cash and cash equivalents	**117,210**	2,077
Cash and cash equivalents at January 1	**323,070**	296,412
Effect of foreign exchange rate changes	**535**	24,581
Cash and cash equivalents at December 31	**440,815**	323,070

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, liver diseases and obesity in the PRC, the USA, Europe and South Korea.

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

2 BASIS OF PREPARATION

The consolidated financial statements for the year ended December 31, 2023 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, 2023 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 new and amended IFRSs issued by the IASB to these financial statements for the current accounting period:

- IFRS 17, *Insurance contracts*
- Amendments to IAS 8, *Accounting policies, changes in accounting estimates and errors: Definition of accounting estimates*
- Amendments to IAS 1, *Presentation of financial statements* and IFRS Practice Statement 2, *Making materiality judgements: Disclosure of accounting policies*
- Amendments to IAS 12, *Income taxes*: *Deferred tax related to assets and liabilities arising from a single transaction*
- Amendments to IAS 12, *Income taxes*: *International tax reform — Pillar Two model rules*

None of these developments had a material effect 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,	
	2023	2022
	RMB'000	*RMB'000*
Interest income from bank deposits	**13,988**	823
Realised gain on wealth management products	**2,284**	42
Net gain on termination of leases	**–**	3,653
Government grants	**470**	280
	16,742	4,798

5 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging:

(a) Finance costs

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Interest on bank loans	**1,359**	173
Interest on lease liabilities	**368**	1,216
	1,727	1,389

(b) Staff costs

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Salaries, wages and other benefits	**100,305**	87,021
Contributions to defined contribution retirement plan (i)	**5,102**	4,602
Equity settled share-based payment expenses	**28,293**	26,461
	133,700	118,084

(c) Other items

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Amortisation of intangible assets	**1,864**	1,070
Depreciation charge		
— property, plant and equipment	**1,632**	2,219
— right-of-use assets	**1,736**	3,299
	3,368	5,518
Impairment loss on property, plant and equipment	**–**	807
Listing expenses	**12,953**	23,896
Auditors' remuneration		
— audit services	**3,000**	3,103
— tax services	**24**	23
	3,024	3,126
Research and development expenses (ii)	**230,485**	313,356
Net foreign exchange loss	**4,182**	3,544

(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, 2023, research and development expenses included staff costs, depreciation and amortisation expenses of RMB92,373,000 in total (2022: RMB83,468,000), 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

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, 2023 and 2022 as there were no assessable profits.

(iii) The USA

The Company's subsidiary incorporated in the USA is subject to Federal Tax at a rate of 21% and State Profits Tax at a rate of 0.75%–9.50% (2022: 0.75%–9.99%). Operations in the USA have incurred net accumulated operating losses for income tax purposes, and no income tax provisions had been made for the year ended December 31, 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 RMB368,814,000 (2022: RMB781,594,000) and the weighted average of 219,592,000 ordinary shares (2022: 76,721,000 shares, after adjusting for the effect of the share subdivision upon the Listing, assuming that the share subdivision had been effected since January 1, 2022) in issue during the year.

8 INTANGIBLE ASSETS

	In-licensed rights *RMB'000*	**Software** *RMB'000*	**Total** *RMB'000*
Cost:			
At January 1, 2022	108,661	1,804	110,465
Additions	–	4,349	4,349
Exchange adjustments	10,037	–	10,037
At December 31, 2022 and January 1, 2023	118,698	6,153	124,851
Additions	–	449	449
Exchange adjustments	2,013	–	2,013
At December 31, 2023	120,711	6,602	127,313
Accumulated amortisation:			
At January 1, 2022	–	(150)	(150)
Charge for the year	–	(1,070)	(1,070)
At December 31, 2022 and January 1, 2023	–	(1,220)	(1,220)
Charge for the year	–	(1,864)	(1,864)
At December 31, 2023	–	(3,084)	(3,084)
Net book value:			
At December 31, 2023	**120,711**	**3,518**	**124,229**
At December 31, 2022	**118,698**	**4,933**	**123,631**

In-licensed rights

The balance of in-licensed rights represents payments made to acquire development and commercialization 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 payment, as well as royalty payment on net sales to Novartis.

(ii) LAE002 & 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 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 regulatory milestone payments, sales milestone payment, as well as royalty payment 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 regulatory milestone payments, sales milestone payment, as well as royalty payment 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 cash-generating unit ("**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 appraiser 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:

	2023	2022
LAE001		
Discount rate	**18%**	18%
Revenue growth rate	**–12% to 83%**	–14% to 379%
Recoverable amount of CGU *(in RMB million)*	**724.2**	573.6
LAE002 & LAE003		
Discount rate	**18%**	18%
Revenue growth rate	**–7% to 523%**	–7% to 456%
Recoverable amount of CGU *(in RMB million)*	**963.6**	1,252.1
LAE005		
Discount rate	**18%**	18%
Revenue growth rate	**–15% to 24%**	–18% to 24%
Recoverable amount of CGU *(in RMB million)*	**278.0**	252.4

Based on the result of the above assessment, there were no impairment for the in-licensed rights as at December 31, 2023 and 2022.

9 TIME DEPOSITS

As at December 31, 2023, time deposits of RMB338,120,000 (2022: nil) in the consolidated statement of financial position represented bank deposits with original maturity over three months.

10 CASH AND CASH EQUIVALENTS

	2023	2022
	RMB'000	*RMB'000*
Cash at banks	**171,626**	267,333
Deposits with banks	**269,189**	55,737
	440,815	323,070

As at December 31, 2023, cash and cash equivalents of the Group situated in Chinese Mainland amounted to RMB207,172,000 (2022: RMB63,180,000). Remittance of funds out of Chinese Mainland is subject to relevant rules and regulations of foreign exchange control.

11 BANK LOANS

	2023	2022
	RMB'000	*RMB'000*
Unsecured bank loans due within 1 year	**49,400**	19,782

As at December 31, 2023, unsecured bank loans carried interest at annual rates ranging from 3.40% to 4.35% (2022: 2.75% to 4.35%) per annum and were all repayable within one year.

12 OTHER PAYABLES

	2023	2022
	RMB'000	*RMB'000*
Payroll payables	**14,279**	14,700
Accrued research and development expenses	**42,939**	51,595
Other payables and accrued charges	**11,227**	9,573
	68,445	75,868

13 FINANCIAL INSTRUMENTS ISSUED TO INVESTORS

	2023	2022
	RMB'000	*RMB'000*
Preferred shares	**–**	2,277,281
Warrant	**–**	–
	–	2,277,281

(a) Preferred shares

In accordance with the Group's accounting policy, the preferred shares were initially recognised at fair value on the date of issuance and were subsequently re-measured to their fair value at the end of each reporting period. Movements of preferred shares for the year ended December 31, 2023 and 2022 were set out below:

	Preferred Shares *RMB'000*
As at January 1, 2022	1,402,111
Issuance of preferred shares	326,006
Fair value changes	378,308
Exchange adjustments	170,856
As at December 31, 2022 and January 1, 2023	2,277,281
Fair value changes	71,210
Exchange adjustments	86,349
Conversion of preferred shares into ordinary shares	(2,434,840)
As at December 31, 2023	–

All preferred shares were converted into ordinary shares of the Company upon the completion of the Listing.

(b) Warrant

In accordance with the Group's accounting policy, the warrant is initially recognised at fair value on the date of issuance and is subsequently re-measured to the fair value at the end of each reporting period. Movements of the warrant for the year ended December 31, 2022 were set out below:

	Warrant *RMB'000*
As at January 1, 2022	98,429
Fair value changes	8,748
Exchange adjustments	(434)
Exercise of the warrant	(106,743)
As at December 31, 2022	–

On March 31, 2022, the warrant was exercised. Accordingly, the Company issued 1,166,525 ordinary shares and 338,273 preferred shares to the investor.

14 DIVIDENDS

The directors of the Company did not propose any payment of dividend for the year ended December 31, 2023 (2022: nil).

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a science-driven, clinical-stage biotechnology company committed to bringing novel therapies to cancer, metabolic diseases and liver fibrosis patients worldwide. As of December 31, 2023, we have initiated six clinical trials for Afuresertib (LAE002), LAE001 and LAE005 to address unmet medical needs in cancers. Among the six clinical trials, three are multi-regional clinical trials (MRCTs). LAE102 is our internally discovered antibody against ActRIIA. We submitted IND applications to CDE and FDA respectively for LAE102 in relation to obesity indication in the first quarter of 2024. Blocking Activin-ActRII pathway could promote skeletal muscle regeneration and decrease fat mass. Laekna team has accumulated tremendous experiences and deep knowhow in this specific field and are developing more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor for ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle regeneration and other disease indications in the drug candidate pipeline.

We have assembled a seasoned management team with extensive experience and expertise covering the full cycle of the 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, 2023, we were supported by a talented R&D team consisting of 62 employees, with 17 holding doctorate degrees and 30 holding master degrees. Our core management team has established a long track record of accomplishment, leadership and deep knowledge in their respective fields.

Since our inception in 2016, we have in-licensed global rights from Novartis on four drug candidates with a clinical proof-of-concept in certain oncology indications, internally discovered fourteen drug candidates, and initiated six clinical trials.

In the cancer area, we have built a comprehensive portfolio of drug candidates including Afuresertib, LAE001 and other eight drug candidates. Afuresertib is a potent AKT inhibitor that inhibits all three AKT isoforms (AKT1, AKT2 and AKT3) as well as one of the only two AKT inhibitors in or completed the pivotal-stage clinical development for anti-cancer treatment globally. Afuresertib has demonstrated several advantages compared to other AKT inhibitors, including higher efficacy, better potency, more significant tumor inhibition exposure and a better safety profile, based on 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 Afuresertib Phase Ib study for HR+/HER2- breast cancer, which was presented in SABCS 2023, the Group has initiated the Phase III pivotal study. We also continue to develop our clinical trials for the treatment of breast cancer, prostate cancer, ovarian cancer and PD-1/PD-L1 drug-resistant solid tumors to address the unmet medical needs. In several clinical trials, the combination of Afuresertib with other therapeutics exhibits favorable efficacy results.

For the internally discovered oncology drug candidates, we have received our first IND approval from FDA on LAE102, an ActRIIA-specific monoclonal antibody, in May 2023. Also, we filed IND to CDE in November 2023, and obtained approval in the first quarter of 2024. Besides of cancer indications, LAE102 has also showed in the pre-clinical studies to increase skeletal muscle and decrease fat mass, a potential drug candidate to be developed for obesity indication. We submitted IND applications to CDE and FDA respectively in relation to obesity indication in the first quarter of 2024. We plan to commence clinical trial process after obtaining IND approval and are committed to bring this precision therapy to obesity patients who are in needs of the novel treatment options. Laekna has been pursuing strategic partnerships to accelerate the development and commercialization of LAE102 for such important indications with a great unmet medical need outside of the cancer therapeutic area. Blocking Activin-ActRII pathway could promote skeletal muscle regeneration and decrease fat mass. Laekna team has accumulated tremendous experiences and deep knowhow in this specific field and are developing more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor for ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle regeneration and other disease indications in the drug candidate pipeline.

Several projects in the pipeline are progressed to the PCC stage. These include LAE103 which is a monoclonal antibody against ActRIIB for indications related to muscle regeneration, LAE105 which is a bi-functional aHSC-NK engager with sHSC killing and anti-fibrosis activity, the FGFR2b-specific mAb (LAE112), bispecific antibodies for LILRB1-B2 (LAE111) and for TIGIT- PVRIG (LAE113) that regulate the function of T/NK cells, and two low molecular weight projects PARP1-selective inhibitors (LAE119) and USP1 inhibitors (LAE120).

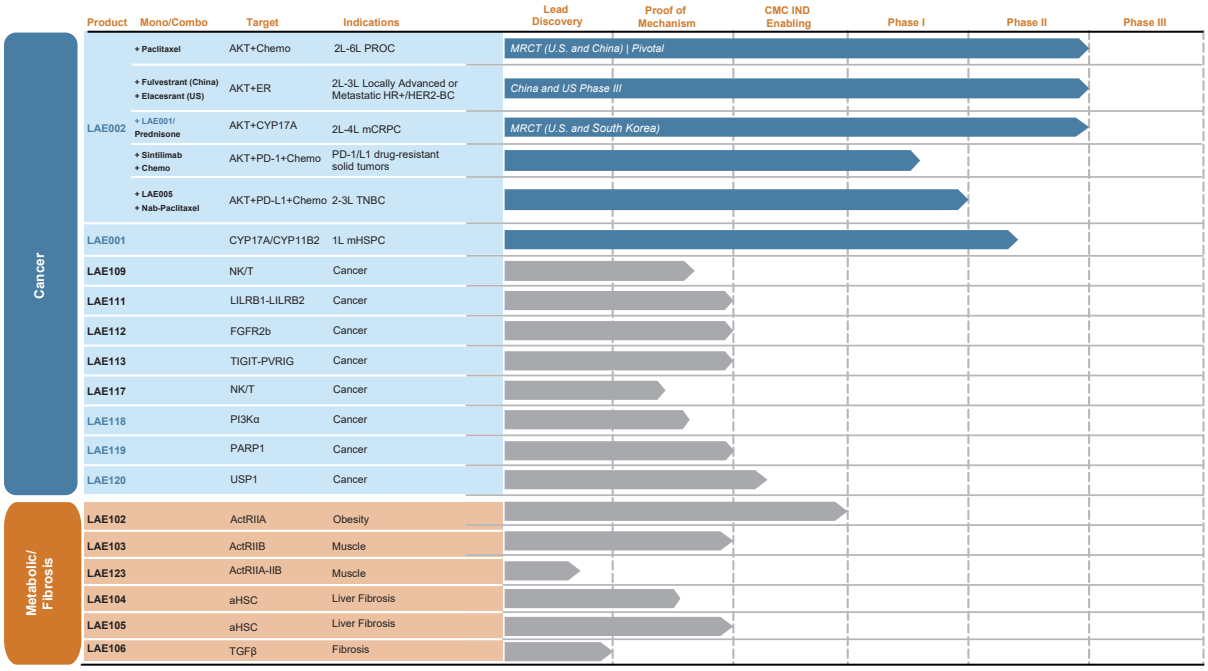
MARKET OPPORTUNITIES IN CANCER AND OBESITY TREATMENTS

Although the field of cancer treatment has progressed significantly in the past decade, a large 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 standard of care (SOC) treatment resistance and/or intolerable toxicity, resulting in large unmet medical needs and socioeconomic burden. Among those cancers of unmet medical needs, 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.

Globally, the number of people living with obesity is set to reach over 1.2 billion by 2030. 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 among both the medical community and the public of the critical need to treat obesity, while an increasing number of people living with such disease are actively seeking support.

PIPELINE

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



BUSINESS REVIEW

The Company was listed on the Stock Exchange on June 29, 2023. The Company has made significant progress in the year ended December 31, 2023 with respect to its drug pipeline and business operations, including the following milestones and achievements.

Afuresertib (LAE002)

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

Afuresertib +Fulvestrant in HR+/HER2-breast cancer

According to Frost & Sullivan, the global and China 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 remains as a huge unmet medical need and a multi-billion dollar market potential.

We have initiated a Phase Ib/III trial in China and the U.S. for the treatment of HR+/HER2- LA/mBC with Afuresertib, in a combination of a SOC treatment fulvestrant. We completed to enroll 20 subjects in Phase Ib trial in April 2023. The results of a Phase Ib study to evaluate the efficacy and safety of afuresertib (LAE002, an oral AKT inhibitor) plus fulvestrant in patients with HR+/HER2- LA/mBC who failed standard of care therapies were presented during a poster spotlight session at the 2023 San Antonio Breast Cancer Symposium (SABCS). The study results are summarized as follows:

LAE205INT3101 (NCT04851613) is an ongoing phase Ib/III global study. The data presented is from the phase Ib single arm, open-label study to evaluate the efficacy and safety of the combination therapy of afuresertib (125mg QD) plus fulvestrant (500mg Q28 days) in patients with HR+/HER2- LA/mBC who have disease progression after 1–2 prior lines of ET with or without a CDK4/6 inhibitor (≤1 line), and/or ≤1 line of chemotherapy.

As of the data cut-off date of October 16, 2023, 20 patients were enrolled, consisting of 17 Chinese patients and 3 American patients. There were 19 female patients and 1 male patient enrolled. The median age of all patients was 53 years old. 80% of the patients had received one line of therapy, and 20% had received two lines of therapy. 70% of the patients were previously treated with CDK4/6 inhibitors. The median duration of follow-up was 11 months.

Efficacy:

- Best overall response: 6 patients had confirmed partial response (30%), 10 patients had stable disease (50%), and 4 patients had progressive disease (20%);

- The confirmed objective response rate was 30% (95%CI, 11.9, 54.3) and the disease control rate was 80%. The median PFS was 7.3 months (95%CI, 3.7, NE);

- Among the 11 patients with specific biomarker alterations (PIK3CA/AKT1/PTEN), the confirmed objective response rate was 45.4% (95%CI, 16.7, 76.6), the disease control rate was 82%, and the median PFS was 7.3 months (95%CI, 3.6, 8.2); and

- Among the 17 Chinese patients, the confirmed objective response rate was 29.4% (95%CI, 10.3, 60.0), the disease control rate was 82.4%, and the median PFS was 7.3 months (95%CI, 3.6, 8.2).

Safety:

- No dose modification was required during the safety run-in. No patient discontinued treatment due to TEAE. No SAE or TEAE > = Grade 4 was reported. The majority of observed TEAEs were Grade 1. Grade 3 AEs were reported in 7 patients, including diarrhea, pharyngitis, ALT/AST, γ-glutamyl transferase, creatine phosphokinase increased, white blood cell count decreased and rash.

Conclusions:

- The preliminary data from the combination therapy of afuresertib plus fulvestrant has shown promising anti-cancer efficacy with a well-tolerated safety profile in patients with HR+/HER2- LA/mBC who had disease progression after 1–2 prior lines of standard of care therapies.

In CAPItello-291 Phase III study conducted by AstraZeneca Plc., which targets the similar patient population, AstraZeneca Plc. has submitted NDA to FDA and was granted with a priority review in June 2023, and obtained FDA's approval in November 2023. Our Phase Ib results have shown promising efficacy and safety profile comparable to CAPItello-291, showing its high potential to be further developed through a registration trial to regulatory approval. We have initiated the Phase III pivotal trial of afuresertib plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer who failed standard of care therapies in 2023.

Afuresertib +LAE001/prednisone in mCRPC

According to Frost & Sullivan, the global and China 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 clinical trial of the MRCT study of LAE001 and prednisone plus Afuresertib 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. The detailed study readouts including efficacy and safety data was presented in the European Society for Medical Oncology (ESMO) Congress in October 2023. As of September 1, 2023, 40 patients 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 7.9 months, 95% CI: (5.7m, NE). This is a significant improvement compared to the median rPFS of 2 to 4 months of mCRPC patients under the standard treatments historically. Among 12 patients with measurable lesions at baseline based on RECIST 1.1, two confirmed PRs and two unconfirmed PRs were observed. The combination therapy was generally tolerable with manageable TEAEs and recoverable after routine treatments. A following Phase III pivotal trial design is under discussion with regulatory agencies.

Afuresertib +Paclitaxel for PROC (PROFECTA-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 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 pivotal trial (PROFECTA-II) in both the U.S. and China to treat PROC patients with Afuresertib plus paclitaxel. It was a Phase II, randomized, open-label, active-controlled study evaluating the efficacy and safety of afuresertib in combination with paclitaxel versus paclitaxel in women with PROC. The study randomized 150 patients to either investigational or control treatment arm in the U.S. and China. The primary endpoint is PFS, as assessed by investigators. Secondary endpoints include overall survival, objective response rate, and duration of response. 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%), study data demonstrated that 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 secondary endpoint overall survival (OS) data observed a positive trend for the biomarker subgroups. The other secondary endpoints showed an increase in objective response rate and longer duration of response. The trial has shown a manageable and tolerable safety profile and adverse events were consistent with the known safety profiles of the individual treatments. The Group will discuss the results with regulatory authorities to identify a registration path for PROC patient populations that may benefit from afuresertib. The details of the trial data will be presented in a medical conference.

In addition, we are also actively conducting other clinical trials to further expand the indications of Afuresertib in other cancers. We are collaborating with Innovent Biologics (Suzhou) Co. Ltd. in a combination therapy with sintilimab targeting patients with solid tumors progressed upon prior PD-1/PD-L1 treatments and/or chemotherapy. A Phase I study was initiated in June 2022 and we are in the process of the dose escalation study as of December 31, 2023. 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.

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 administrated without prednisone, the short-term high dose or long-term exposure of which can lead to a variety of adverse events.

We completed the Phase I clinical trial and initiated the Phase II clinical trial of a Phase I/II study in China to assess the safety and efficacy of LAE001 as a monotherapy at recommended Phase II dose (RP2D) in mCRPC.

LAE005

LAE005 is a high-affinity, ligand-blocking, humanized anti-PD-L1 IgG4 antibody. In the 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 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. We have completed dose escalation phase and determined RP2D. The preliminary efficacy and safety data would be presented at a scientific conference in the second quarter of 2024.

LAE102

LAE102 is our internally discovered antibody against ActRIIA. We submitted IND applications to CDE and FDA respectively for LAE102 in relation to obesity diseases indication in the first quarter of 2024. We plan to commence clinical trial process after obtaining IND approval. Blocking Activin-ActRII pathway could promote skeletal muscle regeneration and decrease fat mass. Laekna team has accumulated tremendous experiences and deep knowhow in this specific field and are developing more drug candidates to maximize the value of targeting ActRII receptors. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor for ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle regeneration and other disease indications in the drug candidate pipeline. We are committed to bring this precision therapy to obesity patients who are in needs of the novel treatment options.

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 RMB11.9 million or 247.9% from RMB4.8 million in 2022 to RMB16.7 million in 2023, which was primarily attributable to the increase in interest income from bank deposits in 2023.

Other Losses

Our other losses increased by RMB1.9 million or 43.2% from RMB4.4 million in 2022 to RMB6.3 million in 2023, which was primarily attributable to the losses on early termination of a purchase contract with a supplier.

Administrative Expenses

Our other administrative expenses decreased by RMB4.3 million or 5.4% from RMB80.2 million in 2022 to RMB75.9 million in 2023, which was primarily attributable to the decrease in listing expenses.

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Staff costs	**46,136**	40,121
Professional service expenses	**10,084**	9,481
Listing expenses	**12,953**	23,896
Others	**6,705**	6,740
Total	**75,878**	80,238

Research and Development Expenses

Our research and development expenses decreased by RMB82.9 million or 26.4% from RMB313.4 million in 2022 to RMB230.5 million in 2023, which was primarily attributable to (i) decreased discovery research expenses from RMB73.2 million in 2022 to RMB25.3 million in 2023 as a result of the pre-clinical candidate LAE102 obtained IND approval in early 2023, and (ii) decreased clinical development expenses from RMB153.6 million in 2022 to RMB108.3 million in 2023, which was primarily attributable to the decreased CMC related service expenses.

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Staff costs	**87,564**	77,963
Discovery research expenses	**25,258**	73,239
Clinical development expenses	**108,335**	153,648
Others	**9,328**	8,506
Total	**230,485**	313,356

Fair Value Changes on Financial Instruments Issued to Investors

Our fair value changes on financial instruments issued to investors decreased by RMB315.9 million or 81.6% from RMB387.1 million in 2022 to RMB71.2 million in 2023. Fair value changes on financial instruments issued to investors were related to preferred shares and warrant. All preferred shares were converted into ordinary shares of the Company upon the completion of the Listing, and the warrant was exercised on March 31, 2022.

Liquidity and Financial Resource

As of December 31, 2023, the current assets of the Group were RMB788.0 million, including cash and cash equivalents of RMB440.8 million, time deposits with an original maturity over three months of RMB338.1 million and other current assets of RMB9.1 million. Among them, the Group's cash and cash equivalents increased by RMB117.7 million or 36.4% to RMB440.8 million as of December 31, 2023 from RMB323.1 million as of December 31, 2022. The Group's time deposits increased to RMB338.1 million as of December 31, 2023 from nil as of December 31, 2022. As of December 31, 2023, the current liabilities of the Group were RMB119.8 million, including other payables of RMB68.5 million, interest-bearing bank loans of RMB49.4 million and current lease liabilities of RMB1.9 million.

Our cash and bank balances (including cash and cash equivalents and time deposits) as of December 31, 2023, were RMB778.9 million, of which RMB29.4 million, RMB653.5 million and RMB96.0 million were denominated in RMB, USD, and HKD, respectively, representing an increase by 141.1% as compared to the cash and bank balances of RMB323.1 million as of December 31, 2022. The increase was primarily attributable to the proceeds from the Global Offering.

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 2023, 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 may require further funding through public or private equity offerings, debt financing and other sources.

Bank Loans

Our bank loans as of December 31, 2023 were RMB49.4 million (December 31, 2022: RMB19.8 million), all of which were denominated in RMB and carried fixed nominal interest rates ranging from 3.40% to 4.35% per annum.

Current ratio

Current ratio (calculated by current assets divided by current liabilities) of the Group as of December 31, 2023, was 6.58 (December 31, 2022: 3.43).

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, 2023, 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, 2023, we did not have any material contingent liabilities.

Significant Investments Held

As of December 31, 2023, the Group did not hold any significant investments. Save as disclosed in this announcement, as of December 31, 2023, the Group did not have future plans for material investments and capital assets.

Pledge of Assets

As of December 31, 2023, we did not pledge any of our assets.

Employees and Remuneration Policies

As of December 31, 2023, the Group had 89 employees.

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. The scheme constitutes a share scheme governed by Chapter 17 of the Listing Rules. For further details of the Pre-IPO Share Option Scheme and the Post-IPO Share Option Scheme, please refer to the sections headed "Statutory and General Information — Pre-IPO Share Option Scheme" and "Statutory and General Information — Post-IPO Share Option Scheme" in Appendix IV to the Prospectus.

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. We intend to apply the net proceeds of HK$724.4 million from the Global Offering (the "**Net Proceeds**") in the same manner and proportions as set out in the Prospectus (after deduction of the underwriting fees and commissions and other estimated expenses payable by the Company in connection with the Global Offering).

The below table sets out the proposed and actual applications of the net proceeds from the Listing Date to December 31, 2023:

Intended use of Net Proceeds	**Net Proceeds from the Global Offering** *(HK$ million)*	**Approximate % of total Net Proceeds**	**Utilized Net Proceeds from the Global Offering as of December 31, 2023** *(HK$ million)*	**Unutilized Net Proceeds from the Global Offering as of December 31, 2023** *(HK$ million)*	**Expected timeline of full utilization of the unutilized Net Proceeds**[(1)]
For rapidly advancing the clinical development and approval of our Core Products, i.e. LAE001 and LAE002	407.8	56.3%	70.2	337.6	Before December 31, 2025
For accelerating the research and development of other existing pipeline products and continuously advancing and improving our pipeline products	150.7	20.8%	31.1	119.6	Before December 31, 2025
For improving our production capabilities and developing our manufacturing capacities	71.7	9.9%	0.5	71.2	Before December 31, 2025
For business development activities and enhancing our global reach	55.1	7.6%	6.8	48.3	Before December 31, 2025
For working capital and other general corporate purposes	39.1	5.4%	24.5	14.6	Before December 31, 2025

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 build our product portfolio and advance the development of our existing drug candidates towards commercialization by continuously executing innovative and tailored clinical trial designs for each of our drug candidates and strengthening our relationships with key external parties, including PIs, KOLs, CROs, SMOs, CDMOs, hospitals and others. We expect to achieve and deliver major development milestones for our drug candidates, including Afuresertib, LAE001, LAE005 and LAE003 to further explore their therapeutic potential.

We will also continue to actively explore potential combination therapy opportunities among our pipeline and with existing approved drugs as well as conventional therapies. Our experience in executing and developing combination therapies among our pipeline, such as Afuresertib and LAE001, to treat the second-generation A/AR drug-resistant mCRPC has well demonstrated our ability to unleash the clinical value of our pipeline products. Our Afuresertib combination trial with Fulvestrant has demonstrated great clinical value to treat HR+/HER2- breast cancer patients who have failed prior standard care treatments of endocrine/anti-estrogen therapies including CDK4/6 inhibitors, a big unmet medical need with huge market potential.

Finally, we hope to expand our drug pipeline through our in-house discovery to address high unmet medical needs of broader underserved patients. We are developing multiple innovative drug candidates including small molecules, bispecific antibodies, and bifunctional NK engagers against cancer cells, activated hepatic stellate cells as well as obesity and metabolic diseases. LAE102 is our internally discovered antibody against ActRIIA. It has showed in the pre-clinical studies to increase skeletal muscle and decrease fat mass, a potential drug candidate to be developed for obesity indication. We submitted IND applications to CDE and FDA respectively in relation to obesity indication in the first quarter of 2024. And we plan to commence clinical trial process after obtaining IND approval and are committed to bring this precision therapy to obesity patients who are in needs of the novel treatment options. Blocking Activin-ActRII pathway could promote skeletal muscle regeneration and decrease fat mass. LAE103 is an ActRIIB-selective antibody and LAE123 is a dual inhibitor for ActRIIA/IIB. Both of them are our internally discovered antibodies for muscle regeneration indications in the drug candidate pipeline. Our innovative drug candidates are in various stages of drug discovery and development, and we plan to have one drug candidate entering the clinical stage each year.

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 from the Listing Date 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 period from the Listing Date 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 period from the Listing Date to the date of this announcement.

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

Other than the securities issued by the Company in the Global Offering, neither the Company nor any of its subsidiaries purchased, redeemed or sold any of the Company's listed securities during the Reporting Period.

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, 2023.

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, 2023 as set out in the preliminary 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. 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 the preliminary announcement.

EVENTS AFTER THE REPORTING PERIOD

Mr. CHAU Kwok Keung tendered his resignation, with effect from January 15, 2024, from his office as an independent non-executive Director, the chairperson of the Audit Committee and a member of the Remuneration Committee, due to his other work commitments. With effect from January 15, 2024, Mr. ZHOU Jian has been appointed as an independent non-executive Director, the chairperson of the Audit Committee and a member of the Remuneration Committee. For details of the change of independent non-executive Director, please refer to the Company's announcement dated January 15, 2024.

Ms. TANG Wing Shan Winza resigned as a joint company secretary of the Company (the "**Joint Company Secretary**") and has ceased to act as an authorised representative of the Company (the "**Authorised Representative**") under Rule 3.05 of the Listing Rules and the representative for acceptance of service of process and notices on behalf of the Company in Hong Kong as required under Rule 19.05 (2) of the Listing Rules and Part 16 of the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) (the "**Process Agent**") with effect from February 2, 2024. Following this, Ms. HO Wing Nga was appointed as the Joint Company Secretary, the Authorised Representative and the Process Agent with effect from February 2, 2024. For details, please refer to the Company's announcement dated February 2, 2024.

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, 2023 containing all the information required by the Listing Rules will be published on the same websites and dispatched (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, Macau Special Administrative Region of the People's Republic of China and Taiwan
"CMC"	chemistry, manufacture and control
"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
"PROC"	platinum resistant ovarian cancer
"Prospectus"	the prospectus of the Company dated June 16, 2023
"Remuneration Committee"	the remuneration committee of the Board
"Reporting Period"	the year ended December 31, 2023
"RMB"	Renminbi, the lawful currency of China
"rPFS"	radiographic progression free survival
"RP2D"	recommended Phase II dose
"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
"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
"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 26, 2024

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.