Laekna, Inc.

來凱醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2105)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2023

The Board of Laekna, Inc. is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2023, together with comparative figures for the same period of 2022, as follows.

In this announcement, "we", "us" 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 expanding of our product pipeline. For the first half of 2023, we made the following milestones and achievements:

Advancing the Clinical Trials

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

The patients have been fully enrolled and the topline data is expected to be available in the late fourth quarter of 2023. We will discuss with FDA and NMPA for NDA submission in the U.S. and in China, respectively, should the topline data meet the NDA criteria.

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

The patient enrollment has been completed for Phase Ib trial in April 2023. The study has showed promising early results and the results will be presented in the fourth quarter of 2023 in an academic cancer conference. We are currently in discussion with the regulatory agencies to initiate a Phase III pivotal trial.

Afuresertib +LAE001/prednisone in mCRPC, Phase II

We have completed the patient enrollment in the U.S. and in South Korea in March 2023. The study demonstrated promising treatment benefit for mCRPC patients. The study readouts will be presented in the upcoming European Society for Medical Oncology (ESMO) Congress 2023. A following pivotal trial design will be discussed with the regulatory agencies.

Afuresertib +LAE005+nab-paclitaxel in TNBC, Phase I

We have completed the dose escalation phase and determined RP2D. The study demonstrated promising treatment benefit for TNBC patients, and the detailed results will be orally presented in the upcoming Chinese Society of Clinical Oncology (CSCO) 2023.

Afuresertib +Sintilimab+paclitaxel in EC and CC, Phase I

We have completed three out of four cohorts of the dose escalation study and 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 chemotherpy.

Discovery of Pre-clinical Candidates

LAE102 IND approval

LAE102 is our first internally discovered antibody. We have obtained the IND approval from FDA in May 2023. We will first investigate LAE102 in cancer indications, and will explore LAE102 late on in other disease indications, such as obesity and metabolic diseases, pulmonary arterial hypertension, etc.

Pre-clinical candidates (PCC) declaration

We have advanced three PCC drug candidates from our internal discovery platform: LAE111, a LILRB1 and LILRB2 bispecific antibody; LAE113, a TIGIT-PVRIG bispecific antibody; and LAE112, a FGFR2b monoclonal antibody.

Expected Upcoming Milestones

Presenting Afuresertib+LAE005+nab-paclitaxel Phase I clinical study results as an oral presentation at the CSCO 2023 in Xiamen, China in September 2023.

Presenting Afuresertib+LAE001 Phase I/II clinical study results as a poster presentation at the ESMO 2023 in Madrid, Spain in October 2023.

Presenting LAE111/LILRB1-2 bispecific antibody as a poster presentation at the Society for Immunotherapy of Cancer's (SITC) 38th annual meeting in San Diego, California, U.S., in November 2023.

Presenting LAE113/TIGIT/PVRIG bispecific antibody as a poster presentation at the SITC 38th annual meeting in San Diego, California, U.S., in November 2023.

Presenting Afuresertib+fulvestrant Phase Ib clinical study results in the fourth quarter of 2023.

FINANCIAL HIGHLIGHTS

	Six months ended June 30,	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Research and development expenses	**102,337**	123,708
Administrative expenses	**35,965**	43,486
Fair value changes on financial instruments issued to investors	**71,210**	132,636
Loss for the period	**216,985**	301,925
Total comprehensive loss for the period	**285,759**	366,412

Our research and development expenses decreased by RMB21.4 million. 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 RMB7.5 million, which 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 automatically converted into ordinary shares of the Company upon the 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 six months ended June 30, 2023 — unaudited

		Six months ended June 30,	
		2023	2022
	Note	***RMB'000***	*RMB'000*
Other income	*4*	**3,243**	260
Other losses		**(9,928)**	(1,739)
Administrative expenses		**(35,965)**	(43,486)
Research and development expenses		**(102,337)**	(123,708)
Loss from operations		**(144,987)**	(168,673)
Finance costs	*5(a)*	**(788)**	(616)
Fair value changes on financial instruments issued to investors		**(71,210)**	(132,636)
Loss before taxation	*5*	**(216,985)**	(301,925)
Income tax	*6*	**–**	–
Loss for the period		**(216,985)**	(301,925)
Other comprehensive income for the period (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		**(40,350)**	(37,643)
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of financial statements of foreign subsidiaries		**(28,424)**	(26,844)
Total comprehensive income for the period		**(285,759)**	(366,412)
Loss per share	*7*		
Basic and diluted *(RMB)*		**(2.63)**	(4.08)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

At June 30, 2023 — unaudited

	Note	**At June 30, 2023** ***RMB'000***	At December 31, 2022 *RMB'000*
Non-current assets			
Property, plant and equipment		**4,535**	5,273
Intangible assets	*8*	**127,160**	123,631
Right-of-use assets		**7,378**	8,246
Other non-current assets		**7,315**	8,083
		146,388	145,233
Current assets			
Prepayments and other receivables		**7,355**	11,561
Financial assets measured at fair value through profit or loss	*9*	**72,309**	–
Cash and cash equivalents	*10*	**837,146**	323,070
		916,810	334,631
Current liabilities			
Bank loans	*11*	**39,828**	19,782
Other payables	*12*	**50,180**	75,868
Lease liabilities		**1,865**	1,859
		91,873	97,509
Net current assets		**824,937**	237,122
Total assets less current liabilities		**971,325**	382,355
Non-current liabilities			
Lease liabilities		**5,905**	6,660
Deferred income		**3,500**	3,500
Financial instruments issued to investors		**–**	2,277,281
		9,405	2,287,441
NET ASSETS/(LIABILITIES)		**961,920**	(1,905,086)
CAPITAL AND RESERVES			
Share capital		**27**	5
Treasury shares		**(2)**	–
Reserves		**961,895**	(1,905,091)
TOTAL EQUITY/(DEFICIT)		**961,920**	(1,905,086)

NOTES TO THE UNAUDITED INTERIM FINANCIAL INFORMATION

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 and liver diseases in the PRC, the U.S., 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

This interim financial information has been prepared in accordance with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, including compliance with International Accounting Standard ("**IAS**") 34, *Interim financial reporting*, issued by the International Accounting Standards Board ("**IASB**"). It was authorised for issue on August 24, 2023.

The interim financial information has been prepared in accordance with the same accounting policies adopted in the 2022 annual financial statements, except for the accounting policy changes that are expected to be reflected in the 2023 annual financial statements. Details of any changes in accounting policies are set out in Note 3.

The preparation of interim financial information in conformity with IAS 34 requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses on a year-to-date basis. Actual results may differ from these estimates.

This interim financial information contains condensed consolidated financial statements and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Group since the 2022 annual financial statements. The condensed consolidated interim financial statements and notes thereon do not include all of the information required for a full set of financial statements prepared in accordance with International Financial Reporting Standards ("**IFRSs**").

3 CHANGES IN ACCOUNTING POLICIES

The Group has applied the following new and amended IFRSs issued by the IASB to this interim financial report 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 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 has had a material effect on how the Group's results and financial position for the current or prior periods have been prepared or presented in this interim financial report. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

4 OTHER INCOME

	Six months ended June 30,	
	2023	2022
	RMB'000	*RMB'000*
Interest income from bank deposits	**2,973**	145
Net unrealised and realised gain on wealth management products	**51**	23
Government grants	**219**	92
	3,243	260

5 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging:

(a) Finance costs

	Six months ended June 30,	
	2023	2022
	RMB'000	*RMB'000*
Interest on bank loans	**595**	4
Interest on lease liabilities	**193**	612
	788	616

(b) Staff costs

	Six months ended June 30,	
	2023	2022
	RMB'000	*RMB'000*
Salaries, wages and other benefits	**41,653**	37,352
Contributions to defined contribution retirement plan	**2,498**	2,148
Equity settled share-based payment expenses	**13,326**	11,976
	57,477	51,476

(c) Other items

	Six months ended June 30,	
	2023	2022
	RMB'000	*RMB'000*
Amortisation of intangible assets	**922**	394
Depreciation charge		
— property, plant and equipment	**840**	1,391
— right-of-use assets	**868**	1,649
	1,708	3,040
Listing expenses	**10,951**	17,068
Research and development expenses (i)	**102,337**	123,708
Net foreign exchange loss	**7,803**	1,738

(i) During the six months ended June 30, 2023 and 2022, research and development expenses include staff costs, depreciation and amortisation expenses of RMB40,251,000 and RMB35,965,000 respectively, in which the respective amounts are 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 profit tax has been made for the six months ended June 30, 2023 and 2022 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%–9.99%. Operations in the U.S. have incurred net accumulated operating losses for income tax purposes, and no income tax provisions has been made for the six months ended June 30, 2023 and 2022.

(iv) Mainland China

Pursuant to the Corporate Income Tax Law of the PRC (the "**CIT**"), the Company's PRC 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 the PRC 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 for the six months ended June 30, 2023 is based on the loss attributable to ordinary equity shareholders of the Company of RMB216,985,000 (six months ended June 30, 2022: RMB301,925,000) and the weighted average of 82,489,000 ordinary shares (six months ended June 30, 2022: 73,982,000 shares, after adjusting for the effect of the share subdivision upon Listing) in issue during the interim period.

The calculation of diluted loss per share for the six months ended June 30, 2023 and 2022 has not included the potential effects of the deemed conversion of the preferred shares and share options issued by the Company, as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the six months ended June 30, 2023 and 2022 are the same as basic loss per share.

8 INTANGIBLE ASSETS

	In-licensed rights *RMB'000*	Software *RMB'000*	Total *RMB'000*
Cost:			
At January 1, 2023	**118,698**	**6,153**	**124,851**
Exchange adjustments	**4,451**	**–**	**4,451**
At June 30, 2023	**123,149**	**6,153**	**129,302**
Accumulated amortisation:			
At January 1, 2023	**–**	**(1,220)**	**(1,220)**
Charge for the period	**–**	**(922)**	**(922)**
At June 30, 2023	**–**	**(2,142)**	**(2,142)**
Net book value:			
At June 30, 2023	**123,149**	**4,011**	**127,160**
At January 1, 2023	**118,698**	**4,933**	**123,631**
Cost:			
At January 1, 2022	108,661	1,804	110,465
Additions	–	1,283	1,283
Exchange adjustments	5,721	–	5,721
At June 30, 2022	114,382	3,087	117,469
Accumulated amortisation:			
At January 1, 2022	–	(150)	(150)
Charge for the period	–	(394)	(394)
At June 30, 2022	–	(544)	(544)
Net book value:			
At June 30, 2022	114,382	2,543	116,925
At January 1, 2022	108,661	1,654	110,315

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 available for commercial use. Due to the inherent uncertainties in the research and development processes, these assets are particularly at risk of impairment if the project is not expected to result in a commercialised product. Key terms of these licenses are set out below:

(i) LAE001

On June 30, 2017, 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 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 share subdivision effective upon Listing). The Group capitalised a total amount of USD1.8 million (equivalent to RMB12.2 million). 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 share subdivision effective upon Listing). The Group capitalised a total amount of USD5.2 million (equivalent to RMB33.5 million). 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

The Group did not perform quantitative impairment test for above intangible assets as of June 30, 2023, since the Group's accounting policy is to perform impairment test annually at December 31, or more frequently if events or changes in circumstances indicate that they might be impaired in accordance with IAS 36, *Impairment of assets*. The Group did not identify any indication that the intangible assets were impaired as of June 30, 2023.

9 FINANCIAL ASSETS MEASURED AT FAIR VALUE THROUGH PROFIT OR LOSS

	At June 30, 2023	At December 31, 2022
	RMB'000	*RMB'000*
Wealth management products	**72,309**	–

The Group's financial assets at fair value through profit or loss mainly represent wealth management products issued by various financial institutions with a floating return.

10 CASH AND CASH EQUIVALENTS

	At June 30, 2023	At December 31, 2022
	RMB'000	*RMB'000*
Cash at banks	**767,431**	267,333
Deposits with banks	**69,715**	55,737
	837,146	323,070

As at June 30, 2023, cash and cash equivalents of the Group held in banks and financial institutions in the mainland China amounted to RMB610,191,000 (2022: RMB63,180,000).

11 BANK LOANS

	At June 30, 2023	At December 31, 2022
	RMB'000	*RMB'000*
Unsecured bank loans due within 1 year	**39,828**	19,782

12 OTHER PAYABLES

	At June 30, 2023	At December 31, 2022
	RMB'000	*RMB'000*
Payroll payables	**4,893**	14,700
Accrued research and development expenses	**23,995**	51,595
Other payables and accrued charges	**21,292**	9,573
	50,180	75,868

13 DIVIDENDS

No dividend has been paid or declared by the Company during the six months ended June 30, 2023 (six months ended June 30, 2022: nil).

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a science-driven, clinical-stage biotechnology company committed to bringing novel therapies to cancer and liver fibrosis patients worldwide. As of June 30, 2023, we have initiated six clinical trials including one registration trial 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).

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 June 30, 2023, we are supported by a talented R&D team consisting of 66 employees, with 17 holding doctorate degrees and 34 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 twelve drug candidates, and initiated six clinical trials and completed two clinical trials around the globe.

In the cancer area, we have built a comprehensive portfolio of drug candidates including Afuresertib, LAE001 and other nine drug candidates. Afuresertib is a potent pan-AKT inhibitor that inhibits all three AKT isoforms (AKT1, AKT2 and AKT3) as well as one of the only two AKT inhibitors in 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. We continue to develop along with Novartis early phase clinical development, such as PROC, and expand the oncology indications by selecting additional combination therapies in different drug-resistant solid tumors that beyond Novartis early clinical development, such as HR+/HER2-breast cancer, mCRPC, TNBC, PD-1-resistant cervical cancer and endometrial cancer, etc. In serval clinical trials, the combination of Afuresertib with other therapeutics also 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. LAE102 has also showed in the pre-clinical studies to increase skeletal muscle and decrease white fat, a potential drug candidate to be developed for obesity and other metabolic disease indications. 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. Several other projects in the pipeline are progressed to or near the PCC stage. These include 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 LMW projects PARP1-selective inhibitors (LAE119) and USP1 inhibitors (LAE120).

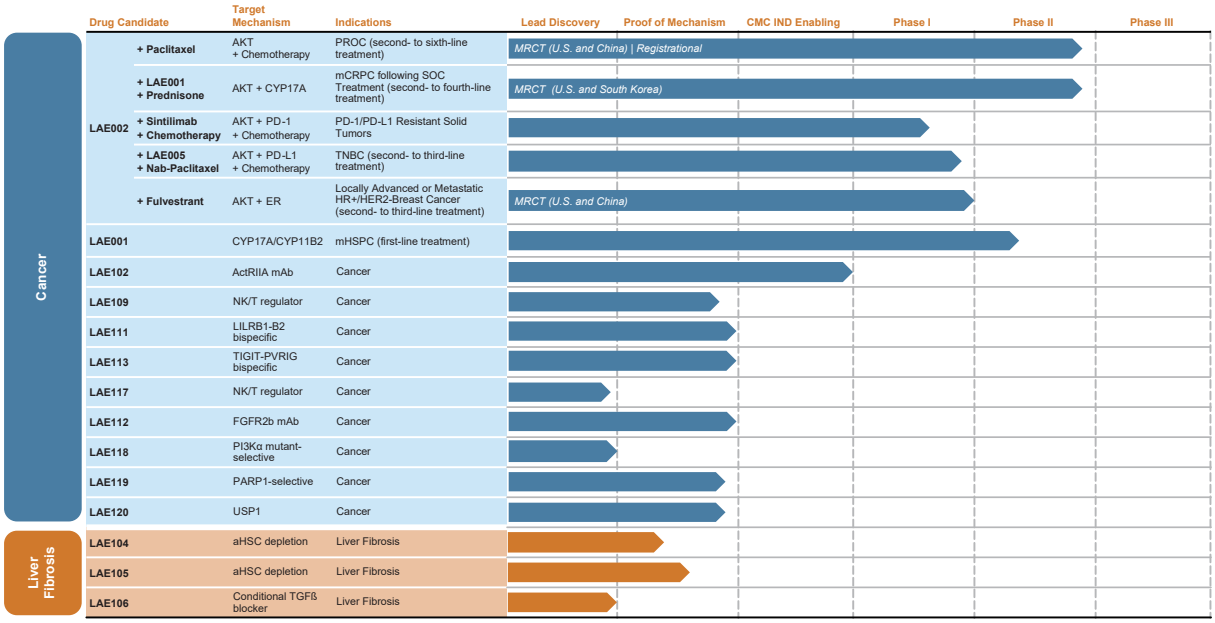
In the liver fibrosis area, we have three pre-clinical drug candidates leveraging on aHSC depletion and conditional TGFß inhibition mechanisms. LAE104, LAE105 are bi-functional aHSC-NK engagers with aHSC killing and anti-fibrosis activity. LAE106 is a conditional TGFß inhibitor, active only in fibrotic tissues. All of these molecules have the potential to prevent or slow down the progression of liver fibrosis, and their therapeutical uses may be expanded to other fibrotic diseases.

MARKET OPPORTUNITIES IN CANCER TREATMENT

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 SOC treatment resistance and/or intolerable toxicity, resulting in large unmet medical needs and socioeconomic burden. Among those cancers of unmet medical needs, platinum-resistant ovarian cancer (PROC), metastatic castration-resistant prostate cancer (mCRPC), HR+/HER2- metastatic breast cancer (HR+/HER2- mBC) and triple negative breast cancer (TNBC) are some of the diseases with limited SOC options and unsatisfactory treatment outcomes.

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 first half of 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. In pre-clinical studies, Afuresertib has demonstrated its ability to restore platinum/paclitaxel sensitivity in PROC cell lines.

- Afuresertib +Paclitaxel for PROC (PROFECTOR-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 registrational trial (PROFECTOR-II) in both the U.S. and China to treat PROC patients with Afuresertib plus paclitaxel. As of June 30, 2023, we had completed the enrollment of pre-defined number of subjects in both the U.S. and China. We expect to have the topline data in the late fourth quarter of 2023. We will discuss with FDA and NMPA for NDA submission in China and the U.S., should the topline data meet the NDA criteria. If the Phase II study cannot fulfil registrational purposes, we will then conduct a randomized, controlled, double blinded Phase III trial or another equivalent trial subjected to the top line results and our communication with the NMPA and the FDA.

- 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 locally advanced or metastatic HR+/HER2- breast cancer with Afuresertib, in a combination of a SOC treatment fulvestrant. We have completed the patient enrollment of Phase Ib trial in April 2023. The study has showed promising early results and we are following the patients for final analysis. We are discussing with regulatory agency and plan to initiate a pivotal Phase III study as soon as we may. In CAPItello-291 Phase III study conducted by AstraZeneca Plc., which targets the similar patient population, the median PFS for capivasertib (AKT inhibitor) combined with fulvestrant vs. placebo combined with fulvestrant was 7.2 months vs. 3.6 months in the overall population; giving an adjusted HR of 0.60 in favor of capivasertib + fulvestrant combination group. AstraZeneca Plc. has submitted NDA to FDA and was granted with a priority review in June 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 plan present the clinical results of Phase Ib study in the fourth quarter of 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 or docetaxel/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 already demonstrated promising treatment benefit for mCRPC patients. The detailed study readouts including efficacy and safety data will be presented in ESMO 2023. Furthermore, we plan to discuss with FDA and NMPA to design and initiate a registration clinical trial and expect to initiate this trial in the second half of 2023.

- 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 currently under patient enrollment.

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 has been selected as an oral presentation at the CSCO 2023.

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

FINANCIAL OVERVIEW

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 RMB2.9 million from RMB0.3 million for the six months ended June 30, 2022, to RMB3.2 million for the six months ended June 30, 2023, which was primarily attributable to the increase in interest income from bank deposits for the six months ended June 30, 2023.

Other Losses

Our other losses increased by RMB8.2 million from RMB1.7 million for the six months ended June 30, 2022, to RMB9.9 million for the six months ended June 30, 2023, which was primarily attributable to the unrealized net foreign exchange losses due to fluctuations in foreign currency exchange rates.

Administrative Expenses

Our administrative expenses decreased by RMB7.5 million from RMB43.5 million for the six months ended June 30, 2022, to RMB36.0 million for the six months ended June 30, 2023. Such decrease was primarily attributable to the decrease in listing expenses.

	Six months ended June 30,	
	2023	2022
	RMB'000	*RMB'000*
	Unaudited	Unaudited
Staff costs	**19,642**	18,059
Professional service expenses	**3,135**	5,482
Listing expenses	**10,951**	17,068
Others	**2,237**	2,877
Total	**35,965**	43,486

Research and Development Expenses

Our research and development expenses decreased by RMB21.4 million from RMB123.7 million for the six months ended June 30, 2022, to RMB102.3 million for the six months ended June 30, 2023. Such decrease was primarily attributable to (i) decreased discovery research expenses from RMB22.5 million for the six months ended June 30, 2022 to RMB11.2 million for the six months ended June 30, 2023 as a result of the pre-clinical candidate LAE102 obtained IND approval in early 2023, and (ii) decreased clinical development expenses from RMB63.9 million for the six months ended June 30, 2022 to RMB49.0 million for the six months ended June 30, 2023, which was primarily attributable to the decreased CMC related service expenses.

	Six months ended June 30,	
	2023	2022
	RMB'000	*RMB'000*
	Unaudited	Unaudited
Staff costs	**37,835**	33,417
Discovery research expenses	**11,214**	22,548
Clinical development expenses	**49,040**	63,887
Others	**4,248**	3,856
Total	**102,337**	123,708

Fair Value Changes on Financial Instruments Issued to Investors

Our fair value changes on financial instruments issued to investors decreased from RMB132.6 million for the six months ended June 30, 2022, to RMB71.2 million for the six months ended June 30, 2023. Fair value changes on financial instruments issued to investors were related to preferred shares and warrant. All preferred shares were automatically 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 Resources

As of June 30, 2023, the current assets of the Group were RMB916.8 million, including cash and cash equivalents of RMB837.1 million and other current assets of RMB79.7 million. Among them, the Group's cash and cash equivalents increased by RMB514.0 million to RMB837.1 million as of June 30, 2023 from RMB323.1 million as of December 31, 2022. As of June 30, 2023, the current liabilities of the Group were RMB91.9 million, including other payables of RMB50.2 million, interest-bearing bank loans of RMB39.8 million and current lease liabilities of RMB1.9 million.

Our cash and bank balances as of June 30, 2023 were RMB837.1 million, of which RMB34.1 million, RMB89.0 million and RMB714.0 million were denominated in RMB, USD, and HKD, respectively representing an increase of 159% as compared to 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. For the six months ended June 30, 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 and Other Borrowings

Our bank loans and other borrowings as of June 30, 2023 were RMB39.8 million (December 31, 2022: RMB19.8 million), all of which were denominated in RMB and carried fixed nominal interest rates ranging from 2.75% to 4.35% per annum. The Group had available unutilized bank loan facilities of approximately RMB10.2 million as of June 30, 2023, same as that as of December 31, 2022.

Current ratio

Current ratio (calculated by current assets divided by current liabilities) of the Group as of June 30, 2023, was 9.98 (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 June 30, 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, 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 June 30, 2023, we did not have any material contingent liabilities.

Significant Investments Held

During the Reporting Period, the Group did not hold any significant investments in equity interest in any company.

Employees and Remuneration Policies

As of June 30, 2023, the Group had 93 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.

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 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$726.5 million from the Global Offering 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).

For the period from the Listing Date up to the date of this announcement, the Company has not utilized the net proceeds raised from the Global Offering. The Company intends to use the net proceeds in the same matter and proportion as set out in the Prospectus under the section headed "Future Plans and Use of Proceeds".

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 and activated hepatic stellate cells. These 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 the 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 14 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

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 INTERIM RESULTS

The Audit Committee, comprising Mr. CHAU Kwok Keung, Dr. WANG David Guowei and Dr. LI Min, has discussed with the management and reviewed the unaudited interim financial information of the Group for the Reporting Period. The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

In addition, the Company's independent auditor, KPMG, has performed an independent review of the Group's interim financial information for the Reporting Period in accordance with Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information performed by the Independent Auditor of the Entity" issued by the Hong Kong Institute of Certified Public Accountants.

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.

INTERIM DIVIDEND

The Board does not declare the payment of an interim dividend to the Shareholders for the Reporting Period.

PUBLICATION OF RESULTS ANNOUNCEMENT AND INTERIM REPORT

This interim results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.laekna.com). The interim report for the six months ended June 30, 2023 containing all the information required by the Listing Rules will be dispatched to the Shareholders and made available on the above websites in due course.

"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
"CG Code"	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
"Chief Executive Officer"	the chief executive officer of our Company
"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", "us" or "our"	our Company and its subsidiaries

"HK$" or "HKD"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"Hong Kong" or "HK"	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
"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 10 to the Listing Rules
"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
"RP2D"	recommended Phase II dose
"Reporting Period"	the six months ended June 30, 2023
"RMB"	Renminbi, the lawful currency of China
"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
"TNBC"	triple-negative breast cancer, any breast cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2
"United States" 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, August 24, 2023

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, Ms. JI Dongmei and Mr. SUN Yuan as non-executive Directors; and Dr. YIN Xudong, Mr. CHAU Kwok Keung and Dr. LI Min as independent non-executive Directors.