LianBio Reports Second Quarter 2023 Financial Results and Provides Corporate Update

August 14, 2023

- *Mavacamten New Drug Application (NDA) under priority review with China National Medical Products Administration (NMPA)*
- *Phase 3 EXPLORER-CN trial of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) met primary endpoint*
- *Data from EXPLORER-CN trial to be presented in an oral late-breaking science session at European Society of Cardiology Congress 2023*
- *Cash, cash equivalents and marketable securities of $267.3 million with runway into the first half of 2025*

SHANGHAI, China and PRINCETON, N.J., Aug. 14, 2023 (GLOBE NEWSWIRE) -- LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today reported financial results for the second quarter ended June 30, 2023.

“During the first half of 2023, we achieved multiple clinical development milestones and advanced our pipeline closer to patients in need of new treatment options,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “Over the next twelve months, we are looking forward to our first anticipated approval in China, building and developing our cardiovascular sales force, filing an NDA to support approval of TP-03 in China, and initiating a pivotal trial of infigratinib in gastric cancer. We believe we are well positioned for LianBio’s first launches in our territories later this year when we begin to commercialize mavacamten in Singapore and Macau.”

Recent Business Highlights and Clinical Development Updates

Mavacamten commercial preparation ongoing in China with NDA under priority review; Asia Pacific regulatory milestones achieved with Singapore and Macau approvals granted and additional NDA under review in Hong Kong

- In the second quarter of 2023, LianBio continued to progress the Company's collaboration with the Chinese Cardiovascular Association (CCA) to develop HCM centers of excellence (COE), with 17 key hospitals now taking part in the CCA's HCM COE pilot program.
- In July 2023, LianBio announced data from the Phase 3 EXPLORER-CN trial of mavacamten in Chinese symptomatic oHCM patients were accepted for a late-breaking presentation at the European Society of Cardiology (ESC) Congress 2023.
- In June 2023, mavacamten was approved for the treatment of adults with symptomatic oHCM in Singapore.
- In May 2023, mavacamten was approved for the treatment of adults with symptomatic New York Heart Association Class II-III oHCM in the Macau Special Administrative Region.
- In April 2023, LianBio announced topline results from the Phase 3 EXPLORER-CN trial evaluating mavacamten in Chinese patients with oHCM. EXPLORER-CN met the primary endpoint, demonstrating statistically significant and clinically meaningful improvement in Valsalva left ventricular outflow tract gradient from baseline to week 30 compared to placebo. Mavacamten also demonstrated improvement across all secondary endpoints. Mavacamten demonstrated a safety profile consistent with previous studies.
- In April 2023, the China NMPA accepted with priority review the NDA for mavacamten for the treatment of adults with symptomatic oHCM.

Registrational Phase 3 LIBRA clinical trial of TP-03 for the treatment of Chinese Demodex blepharitis patients completed enrollment; TP-03 approved in the United States

- In July 2023, LianBio partner Tarsus Pharmaceuticals announced the U.S. Food and Drug Administration's approval of TP-03 for the treatment of adults with Demodex blepharitis.
- In June 2023, LianBio announced completion of enrollment in the Phase 3 LIBRA clinical trial of TP-03 in Chinese Demodex blepharitis patients. LianBio expects the LIBRA trial to support TP-03 registration in China.

Positive topline data announced from Phase 2a trial of infigratinib in Chinese patients with gastric cancer and receipt of Breakthrough Therapy Designation in China

- In June 2023, LianBio announced topline results from the Company’s Phase 2a proof of concept trial evaluating infigratinib in patients with third-line or later gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 (FGFR2) gene amplification. The trial demonstrated a confirmed objective response rate (ORR) of 25.0% (n=20). The observed mediation duration of response was 3.8 months.

- Based on these data, the NMPA granted Breakthrough Therapy Designation to infigratinib for the treatment of gastric cancer.

Phase 1 clinical trial of SHP2 inhibitor BBP-398 in combination with osimertinib in Chinese non-small cell lung cancer (NSCLC) patients with EGFR mutations initiated

- In August 2023, LianBio announced the initiation of a Phase 1 trial of BBP-398 in combination with osimertinib in Chinese NSCLC patients with EGFR mutations.
- In July 2023, LianBio entered into a clinical supply agreement with AstraZeneca in China to procure osimertinib for this clinical trial.

Commercial infrastructure build continues with Chief Commercial Officer appointment

- In April 2023, Pascal Qian was promoted to Chief Commercial Officer to oversee the continued growth of the company's commercial capabilities. He will continue to also serve as the company's China General Manager.

Business is well-positioned to achieve anticipated milestones

- Current cash runway is projected to extend into the first half of 2025.

Key Anticipated Milestones

Mavacamten

- LianBio expects to begin enrolling patients in BMS's ongoing Phase 3 ODYSSEY-HCM trial of mavacamten in non-obstructive HCM (nHCM) in China in mid-2024.
- LianBio anticipates NDA approval in China in mid-2024, and commercial launch in China in the second half of 2024.
- LianBio expects to launch mavacamten in Singapore and Macau in the fourth quarter of 2023.
- LianBio plans to file NDAs to support mavacamten approval in Taiwan and Thailand in the fourth quarter of 2023.

TP-03

- LianBio expects to report topline data from the Phase 3 LIBRA trial of TP-03 in Chinese patients with Demodex blepharitis in the fourth quarter of 2023.

Infigratinib

- Data from the Phase 2a clinical trial of infigratinib in locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 gene amplification were accepted for a poster presentation at the European Society of Medical Oncology (ESMO) Congress 2023, to be held October 20-24 in Madrid.
- LianBio expects to initiate a pivotal Phase 2 trial of infigratinib in locally advanced or metastatic gastric cancer patients with FGFR2 gene amplification in the first half of 2024 to support regulatory approval in China.

BBP-398

- LianBio expects to initiate a Phase 1 clinical trial of BBP-398 in combination with a PD-1 inhibitor in advanced solid tumors in the first half of 2024.

Second Quarter 2023 Financial Results

Research & Development Expenses

Research and development expenses were $9.5 million for the second quarter of 2023 compared to $28.6 million for the second quarter of 2022, and $20.3 million for the six month period ended June 30, 2023 compared to $40.9 million for the six month period ended June 30, 2022. The decrease was primarily attributable to increased milestone payments in 2022 and was partially offset by higher development activities to support clinical trials in 2023.

General & Administrative Expenses

General and administrative expenses were $15.6 million for the second quarter of 2023 compared to $14.6 million for the second quarter of 2022, and $30.7 million for the six month period ended June 30, 2023 compared to $30.6 million for the six month period ended June 30, 2022. The increase was primarily attributable to increases in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and was partially offset by lower expenses for legal, consulting and accounting services.

Net Loss

Net loss was $21.6 million for the second quarter of 2023 compared to net loss of $42.4 million for the second quarter of 2022, and $45.7 million for the

six month period ended June 30, 2023 compared to $70.1 million for the six month period ended June 30, 2022.

Cash Balance

Cash, cash equivalents, marketable securities and restricted cash at June 30, 2023 totaled $267.3 million compared to $302.4 million as of December 31, 2022. LianBio projects its current cash, cash equivalents, marketable securities, and restricted cash will be sufficient to fund its current operating plan into the first half of 2025.

About LianBio

LianBio is a cross-border biotechnology company on a mission to bring transformative medicines to historically underserved patients in China and other Asian markets. Through partnerships with highly innovative biopharmaceutical companies around the world, LianBio is advancing a diversified portfolio of clinically validated product candidates with the potential to drive new standards of care across cardiovascular, oncology, ophthalmology, and inflammatory disease indications. LianBio is establishing an international infrastructure to position the Company as a partner of choice with a platform to provide access to China and other Asian markets. For more information, please visit www.lianbio.com.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements. The words “anticipate,” “plan,” “believe,” “continue,” “estimate,” “expect,” “potential,” “may,” “project,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release include, but are not limited to, statements concerning the Company's expectations regarding approval of its NDA for mavacamten in China and the submission of NDAs in Taiwan and Thailand; the Company’s plans and expectations with respect to the initiation and completion of its clinical trials, including the Phase 3 ODYSSEY-HCM trial of mavacamten in non-obstructive HCM, the Phase 2 clinical trial of infigratinib in patients with FGFR2 gene amplification and the Phase 1 clinical trial of BBP-398 in combination with osimertinib in NSCLC; the Company’s plans to present and report results and data from the Phase 3 LIBRA trial of TP-03 and the Phase 2a clinical trial of infigratinib; the advancement of its pipeline of therapeutic candidates; the continued growth of its organization; its ability to bring transformative medicines to patients in China and across Asia; its ability to navigate complex regulatory environments in Greater China and Asia; the Company's plans and expectations with respect to preparation for potential commercialization and product launch, including the anticipated commercial launch of mavacamten in China, Singapore and Macau; and the timeline through which it expects to be able to fund its operating expenses and capital expenditure requirements, as well as statements regarding its partners’ announced plans and expectations with respect to their planned product development activities, preclinical studies and clinical trials. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company’s ability to successfully initiate and conduct its planned clinical trials and complete such clinical trials and obtain results on its expected timelines, or at all; the Company’s plans to leverage data generated in its partners’ global registrational trials and clinical development programs to obtain regulatory approval and maximize patient reach for its product candidates; the Company’s ability to identify new product candidates and successfully acquire such product candidates from third parties; competition from other biotechnology and pharmaceutical companies; general market conditions; the impact of changing laws and regulations and those risks and uncertainties described in LianBio’s filings with the U.S. Securities and Exchange Commission (SEC), including LianBio’s Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and LianBio specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. Readers should not rely upon this information as current or accurate after its publication date.

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LianBio
Consolidated Balance Sheets
(In thousands, except share and per share amounts) (Unaudited)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 104,059	$ 79,221
Marketable securities	163,209	223,142
Prepaid expenses and other current assets	4,805	8,640
Other receivable	1,025	1,770
Total current assets	273,098	312,773
Restricted cash, non-current	69	73
Property and equipment, net	2,562	3,116

Operating lease right-of-use assets	3,049	3,978
Other non-current assets	20	20
Total assets	$ 278,798	$ 319,960
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,908	$ 1,453
Accrued expenses	16,879	19,826
Current portion of operating lease liabilities	1,859	1,851
Other current liabilities	996	485
Total current liabilities	21,642	23,615
Operating lease liabilities	1,441	2,488
Other liabilities	210	210
Nonrefundable research deposit	—	—
Total liabilities	$ 23,293	$ 26,313
Commitments and contingencies (Note 8)		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of June 30, 2023; 107,167,609 shares issued and outstanding at June 30, 2023; Authorized 2,923,900,005 shares as of December 31, 2022; 107,043,924 shares issued and outstanding at December 31, 2022	2	2
Additional paid-in capital	741,246	732,476
Accumulated other comprehensive loss	(3,326)	(2,080)
Accumulated deficit	(516,191)	(470,525)
Total LianBio shareholders' equity	221,731	259,873
Non-controlling interest	33,774	33,774
Total shareholders' equity	255,505	293,647
Total liabilities and shareholders' equity	$ 278,798	$ 319,960

LianBio
Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 9,454	$ 28,591	20,285	40,920
General and administrative	15,590	14,551	30,728	30,639
Total operating expenses	25,044	43,142	51,013	71,559
Loss from operations	(25,044)	(43,142)	(51,013)	(71,559)
Other income:				
Interest income, net	2,754	553	5,160	833
Other income, net	869	203	825	620
Net loss before income taxes	(21,421)	(42,386)	(45,028)	(70,106)
Income taxes	200	5	638	11
Net loss	(21,621)	(42,391)	(45,666)	(70,117)
Other comprehensive income (loss):				
Foreign currency translation loss, net of tax	(1,641)	(421)	(1,537)	(814)
Unrealized gain (loss) on marketable securities, net of tax	(154)	(291)	291	(1,114)
Comprehensive loss	$ (23,416)	$ (43,103)	$ (46,912)	$ (72,045)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.20)	$ (0.39)	$ (0.43)	$ (0.65)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	107,164,401	107,922,501	107,163,220	107,600,767