LianBio Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 13, 2023

- *Entered into agreement with Bristol Myers Squibb for mavacamten in China and other Asian markets*
- *Phase 3 data from EXPLORER-CN trial of mavacamten presented in an oral late-breaking science session at the European Society of Cardiology Congress 2023 with simultaneous publication in JAMA Cardiology*
- *Topline data announced from Phase 3 trial of TP-03 in Chinese Demodex blepharitis patients*
- *Cash, cash equivalents and marketable securities of $252.2 million as of September 30, 2023*
- *Strategic review ongoing*

SHANGHAI and PRINCETON, N.J., Nov. 13, 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 third quarter ended September 30, 2023.

“We continue to make significant progress bringing innovative medicines to patients in our region, including the achievement of critical clinical development and market building milestones,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “Following our recent transaction granting development and commercial rights to BMS for mavacamten in our territories, we look forward to conducting a comprehensive strategic review aimed at realizing the value of our platform and product candidates.”

Recent Business Highlights and Clinical Development Updates

Entered into agreement with Bristol Myers Squibb for mavacamten in China and Other Asian markets

- In October 2023, LianBio entered into an agreement with Bristol Myers Squibb (BMS), whereby BMS obtained LianBio’s exclusive rights to develop and commercialize mavacamten in Mainland China, Hong Kong, Macau, Taiwan, Singapore and Thailand, in conjunction with termination of the exclusive license agreement LianBio previously entered into with MyoKardia, Inc., now a wholly owned subsidiary of BMS, in August 2020 to acquire such rights. Under the terms of the agreement, LianBio is entitled to receive a total consideration of $350 million.
- In August 2023, LianBio announced data from the Phase 3 EXPLORER-CN trial of mavacamten in Chinese symptomatic obstructive hypertrophic cardiomyopathy (oHCM) patients were presented in a late-breaking science session at the European Society of Cardiology (ESC) Congress 2023 and simultaneously published in a *JAMA Cardiology* paper titled, “Effect of Mavacamten on Chinese Patients With Symptomatic Obstructive Hypertrophic Cardiomyopathy.”

Topline data announced from Phase 3 LIBRA clinical trial of TP-03 for the treatment of Chinese Demodex blepharitis patients; TP-03 approved in the United States

- In October 2023, LianBio announced topline data from the Phase 3 LIBRA study of TP-03 in Chinese patients with Demodex blepharitis. The co-primary endpoints of the LIBRA trial were mite eradication (mite density of 0 mites per lash) and complete collarette cure (collarette score of 0) at day 43. Results demonstrated statistically significant mite eradication in patients with *Demodex* blepharitis treated with TP-03 compared to vehicle ($p<0.001$). A positive, although not statistically significant trend ($p=0.15$) was demonstrated for complete collarette cure. LianBio plans to discuss these results with the China National Medical Products Administration (NMPA) and expects to use these data to support a New Drug Application filing in China.
- 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.

Positive topline data presented from Phase 2a trial of infigratinib in Chinese patients with gastric cancer

- In October 2023, LianBio announced data from a Phase 2a study evaluating infigratinib in patients with third-line or later gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 (FGFR2) gene amplification were presented at the European Society for Medical Oncology (ESMO) Congress 2023. The data demonstrated confirmed objective response rate (cORR) of 23.8% (95% CI: 8.2 – 47.2), disease control rate (DCR) of 76.2% (95% CI: 52.8 – 91.8) and median duration of response (DOR) of 3.8 months (95% CI: 3.6 – NE). Median progression-free survival (mPFS) was 3.3 months (95% CI: 2.3 – 4.5) and median overall survival (mOS) was 8.0 months (95% CI: 4.1 – NE).

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

- 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.

Comprehensive strategic review ongoing

- In October 2023, LianBio announced that the company's Board of Directors initiated a comprehensive strategic review of the company, with an update anticipated in the first half of 2024.

Third Quarter 2023 Financial Results

Research & Development Expenses

Research and development expenses were $9.0 million for the third quarter of 2023 compared to $8.3 million for the third quarter of 2022, and $29.3 million for the nine month period ended September 30, 2023 compared to $49.2 million for the nine month period ended September 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 $17.3 million for the third quarter of 2023 compared to $16.3 million for the third quarter of 2022, and $48.0 million for the nine month period ended September 30, 2023 compared to $46.9 million for the nine month period ended September 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 $24.0 million for the third quarter of 2023 compared to net loss of $21.9 million for the third quarter of 2022, and $69.7 million for the nine month period ended September 30, 2023 compared to $92.0 million for the nine month period ended September 30, 2022.

Cash Balance

Cash, cash equivalents, marketable securities and restricted cash at September 30, 2023 totaled $252.2 million compared to $302.4 million as of December 31, 2022.

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 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.

For investor inquiries, please contact:

E: IR@lianbio.com

For media inquiries, please contact:

Katherine Smith, Evoke Canale

E: katherine.smith@evokegroup.com

T: (619) 849-5378

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 103,457	$ 79,221
Marketable securities	148,765	223,142
Prepaid expenses and other current assets	4,673	8,640
Other receivable	910	1,770
Total current assets	257,805	312,773
Restricted cash, non-current	69	73
Property and equipment, net	2,364	3,116
Operating lease right-of-use assets	2,644	3,978
Other non-current assets	20	20
Total assets	$ 262,902	$ 319,960
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 6,229	$ 1,453
Accrued expenses	15,882	19,826
Current portion of operating lease liabilities	1,893	1,851
Other current liabilities	1,623	485
Total current liabilities	25,627	23,615
Operating lease liabilities	950	2,488
Other liabilities	213	210
Total liabilities	$ 26,790	$ 26,313
Commitments and contingencies (Note 8)		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of September 30, 2023; 107,168,686 shares issued and outstanding at September 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	745,786	732,476
Accumulated other comprehensive loss	(3,220)	(2,080)
Accumulated deficit	(540,230)	(470,525)
Total LianBio shareholders' equity	202,338	259,873
Non-controlling interest	33,774	33,774
Total shareholders' equity	236,112	293,647
Total liabilities and shareholders' equity	$ 262,902	$ 319,960

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 9,018	$ 8,258	$ 29,303	$ 49,178
General and administrative	17,283	16,291	48,011	46,930
Total operating expenses	26,301	24,549	77,314	96,108
Loss from operations	(26,301)	(24,549)	(77,314)	(96,108)
Other income:				
Interest income, net	2,707	1,405	7,867	2,238
Other income, net	141	1,253	966	1,873

Net loss before income taxes	(23,453)	(21,891)	(68,481)	(91,997)
Income taxes	586	6	1,224	17
Net loss	(24,039)	(21,897)	(69,705)	(92,014)
Other comprehensive income (loss):				
Foreign currency translation loss, net of tax	(130)	(2,282)	(1,667)	(3,096)
Unrealized gain (loss) on marketable securities, net of tax	236	(160)	527	(1,274)
Comprehensive loss	$ (23,933)	$ (24,339)	$ (70,845)	$ (96,384)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.22)	$ (0.20)	$ (0.65)	$ (0.85)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	107,167,691	108,353,831	107,164,699	107,854,547