LianBio Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 11, 2023

- *Phase 3 trial of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) met primary endpoint*
- *China National Medical Products Administration (NMPA) accepted mavacamten New Drug Application (NDA) with priority review*
- *Mavacamten commercial launch preparations continue in China, supported by the promotion of Pascal Qian to Chief Commercial Official*
- *Cash, cash equivalents and marketable securities of $286.5 million with runway through the end of 2024*

SHANGHAI, China and PRINCETON, N.J., May 11, 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 first quarter ended March 31, 2023.

“We continue to achieve multiple significant milestones, propelling the company towards the anticipated commercial launch of mavacamten in China,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “Our team’s demonstrated proficiency in navigating the Chinese regulatory landscape instills confidence in our cross-border model. With the recent progress we’ve made, we believe we are on track to bring our first drug to market in China next year, while we continue to advance our other key programs through the clinic.”

Recent Business Highlights and Clinical Development Updates

Mavacamten late-stage clinical development and launch readiness activities on track in China with NDA on file; mavacamten approved in Macau; NDAs under review in Singapore and Hong Kong

- In January 2023, mavacamten was added to The Joint Committee of Cardiomyopathy Specialty Alliance, National Center for Cardiovascular Diseases/Cardiovascular Precision Medicine Branch of China International Exchange and Promotive Association for Medical and Health Care’s 2023 Guidelines for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy.
- In April 2023, the China NMPA accepted with priority review the NDA for mavacamten for the treatment of adults with symptomatic oHCM.
- 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 demonstrated a safety profile consistent with previous studies.
- 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.

Commercial infrastructure build continues in preparation for anticipated 2024 mavacamten launch

- In April 2023, Pascal Qian was promoted to Chief Commercial Officer to oversee the continued growth of the company’s commercial capabilities in preparation for the anticipated mavacamten commercial launch in China. 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 through the end of 2024.

Key Anticipated Milestones

Mavacamten

- LianBio plans to present detailed results from EXPLORER-CN at an upcoming medical meeting.

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

- LianBio expects to report topline data from the ongoing Phase 2a clinical trial of infigratinib in locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 gene amplification and other advanced solid tumors with FGFR genomic alterations in the second half of 2023.
- 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 an EGFR-inhibitor in non-small cell lung cancer in the second half of 2023.

First Quarter 2023 Financial Results

Research & Development Expenses

Research and development expenses were $10.8 million for the first quarter of 2023 compared to $12.3 million for the first quarter of 2022. The decrease was primarily attributable to increased milestone payments in 2022, and was offset by higher development activities to support clinical trials in 2023.

General & Administrative Expenses

General and administrative expenses were $15.1 million for the first quarter of 2023 compared to $16.1 million for the first quarter of 2022. The decrease was primarily attributable to decreases in expenses for legal, consulting and accounting services.

Net Loss

Net loss was $24.0 million for the first quarter of 2023 compared to net loss of $27.7 million for the first quarter of 2022.

Cash Balance

Cash, cash equivalents, marketable securities and restricted cash at March 31, 2023 totaled $286.6 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 through the end of 2024.

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 plans and expectations with respect to the initiation and completion of its clinical trials, including the Phase 2 clinical trial of infigratinib in patients with FGFR2 gene amplification and a Phase 1 clinical trial of BBP-398 in combination with an EGFR-inhibitor in non-small cell lung cancer; the Company’s plans to present and report results and data from EXPLORER-CN, the Phase 3 LIBRA trial of TP-03 and the ongoing 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; 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, 2021 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)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 102,334	$ 79,221
Marketable securities	184,203	223,142
Prepaid expenses and other current assets	8,500	8,640
Other receivable	1,013	1,770
Total current assets	296,050	312,773
Restricted cash, non-current	73	73
Property and equipment, net	2,836	3,116
Operating lease right-of-use assets	3,604	3,978
Other non-current assets	20	20
Total assets	$ 302,583	$ 319,960
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 5,431	$ 1,453
Accrued expenses	16,627	19,826
Current portion of operating lease liabilities	1,906	1,851
Other current liabilities	1,961	485
Total current liabilities	25,925	23,615
Operating lease liabilities	2,014	2,488
Other liabilities	217	210
Nonrefundable research deposit	—	—
Total liabilities	$ 28,156	$ 26,313
Commitments and contingencies (Note 8)		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of March 31, 2023; 107,164,175 shares issued and outstanding at March 31, 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	736,752	732,476
Accumulated other comprehensive loss	(1,531)	(2,080)
Accumulated deficit	(494,570)	(470,525)
Total LianBio shareholders' equity	240,653	259,873
Non-controlling interest	33,774	33,774
Total shareholders' equity	274,427	293,647
Total liabilities and shareholders' equity	$ 302,583	$ 319,960

LianBio
Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 10,831	$ 12,329
General and administrative	15,138	16,088
Total operating expenses	25,969	28,417
Loss from operations	(25,969)	(28,417)
Other income (expense):		
Interest income, net	2,406	280
Other (expense) income, net	(44)	417
Net loss before income taxes	(23,607)	(27,720)
Income taxes	438	6
Net loss	(24,045)	(27,726)
Other comprehensive income (loss):		
Foreign currency translation income (loss), net of tax	104	(393)
Unrealized gain (loss) on marketable securities, net of tax	445	(823)
Comprehensive loss	$ (23,496)	$ (28,942)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.22)	$ (0.26)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	107,162,025	107,275,458