LianBio Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 12, 2022

- *LianBio's partner, Bristol Myers Squibb, has received U.S. FDA approval of mavacamten for the treatment of patients with obstructive hypertrophic cardiomyopathy (oHCM)*
- *Registrational Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with symptomatic oHCM ongoing*
- *LianBio's partner, Tarsus, announced positive topline data from the Phase 3 Saturn-2 clinical trial of TP-03 in patients with Demodex blepharitis*
- *LianBio's partner, ReViral, entered into definitive agreement to be acquired by Pfizer*
- *Three additional pipeline programs expected to enter into registrational Phase 3 clinical trials in China by year-end 2022*
- *Cash balance of $389.1 million at the end of first quarter 2022 with runway through mid- 2024*

SHANGHAI, China and PRINCETON, N.J., May 12, 2022 (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, 2022 and provided a corporate update.

"LianBio continues to solidify our standing as the partner of choice to bring clinically validated therapeutic candidates to Greater China and other Asian markets," said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "Several of our partners have recently reached significant global milestones, including a U.S. FDA approval, positive pivotal trial results, and an acquisition. We congratulate our development partners on these important achievements. In China, we are committed to accelerating patient access to potentially transformative therapeutics, and we remain on track to complete enrollment in our ongoing Phase 3 EXPLORER-CN trial of mavacamten and to initiate three additional pivotal studies this year."

Recent Business Highlights and Clinical Development Updates

BMS receives FDA approval for mavacamten and presents additional positive Phase 3 clinical trial results

- In April 2022, LianBio's partner Bristol Myers Squibb (BMS) presented data from two clinical trials of mavacamten at the American College of Cardiology 71st Annual Scientific Session. Data from the EXPLORER-LTE clinical trial demonstrated sustained improvements in clinically meaningful cardiovascular outcomes at weeks 48 and 84 in patients with symptomatic oHCM receiving mavacamten. Data from the Phase 3 VALOR-HCM clinical trial demonstrated the addition of mavacamten significantly reduced the need for septal reduction therapy (SRT) in patients with severely symptomatic oHCM who had been appropriate for SRT at baseline.
- In April 2022, BMS announced the U.S. Food and Drug Administration (FDA) approval of mavacamten for the treatment of adults with symptomatic New York Heart Association Class II-III oHCM to improve functional capacity and symptoms.

Mavacamten development progress continues in China

- In January 2022, LianBio initiated the Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with symptomatic oHCM. Patient enrollment is ongoing.
- In February 2022, the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted Breakthrough Therapy Designation in China for mavacamten for the treatment of patients with oHCM.
- In May 2022, LianBio announced topline results from the Phase 1 pharmacokinetic (PK) study of mavacamten in healthy Chinese volunteers. A single oral administration of mavacamten in Chinese healthy adult subjects showed no new safety signals. The data demonstrated a favorable PK, safety and tolerability profile comparable to that observed in the Phase 1 pharmacokinetic study of mavacamten conducted by LianBio's partner, MyoKardia, now a wholly owned subsidiary of BMS, in healthy volunteers in the United States.

TP-03 met all primary and secondary endpoints in Tarsus's second U.S. pivotal trial

- In May 2022, Tarsus announced positive topline data from the Phase 3 Saturn-2 clinical trial of TP-03 in Demodex blepharitis (DB) patients. The clinical trial met all primary and secondary endpoints and TP-03 was well-tolerated.

- Based on these data, Tarsus announced that it will submit a New Drug Application to the U.S. FDA in the second half of 2022.

Development partner ReViral Ltd. entered into definitive agreement to be acquired by Pfizer Inc.

- In April 2022, Pfizer and ReViral entered into a definitive agreement under which Pfizer will acquire ReViral and its respiratory syncytial virus therapeutic candidates, including sisunatovir.

Formation of Scientific Advisory Board

- In April 2022, LianBio formed a Scientific Advisory Board (SAB). The LianBio SAB is comprised of industry leaders in global drug development who are serving as strategic advisors to the Company.

Appointment to the Board of Directors

- In April 2022, LianBio appointed Wei Wei Chen to the Board of Directors. Ms. Chen brings over 17 years of experience serving as chief financial officer of companies in the consumer, retail and healthcare sectors.

Business is well-positioned to achieve anticipated milestones

- Current cash runway is projected to extend through mid-2024.

Key Milestones Anticipated in 2022

Mavacamten

- Enrollment is ongoing in the EXPLORER-CN Phase 3 clinical trial of mavacamten in Chinese patients with oHCM. LianBio expects to complete enrollment in the second half of 2022.

TP-03

- LianBio remains on track to initiate a Phase 3 clinical trial of TP-03 in Chinese patients with DB in the second half of 2022 to support regulatory approval in China.

NBTXR3

- LianBio expects to begin dosing Chinese patients in Nanobiotix's ongoing global pivotal Phase 3 NANORAY-312 clinical trial of NBTXR3 for the treatment of locally advanced head and neck squamous cell carcinoma in elderly patients ineligible for cisplatin in the second half of 2022.

Infigratinib

- Enrollment is ongoing in LianBio's Phase 2a clinical trial of infigratinib in locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 (FGFR2) gene amplification and other advanced solid tumors with FGFR genomic alterations.

- LianBio expects to begin dosing Chinese patients in QED's ongoing global pivotal Phase 3 PROOF-301 clinical trial of infigratinib in first-line cholangiocarcinoma (CCA) patients with FGFR2 gene fusions/translocations in the second half of 2022.

First Quarter 2022 Financial Results

Research & Development Expenses
Research and development expenses were $12.3 million for the first quarter of 2022 compared to $53.4 million for the first quarter of 2021. The decrease was primarily attributable to increased milestone payments in 2021, and was offset by higher development activities to support clinical trials and personnel-related expenses in 2022.

General & Administrative Expenses
General and administrative expenses were $16.1 million for the first quarter of 2022 compared to $7.1 million for the first quarter of 2021. The increase was primarily attributable to increases in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and higher expense for legal, consulting and accounting services.

Net Loss
Net loss was $27.7 million for the first quarter of 2022 compared to net loss of $61.6 million for the first quarter of 2021.

Cash Balance

Cash, cash equivalents, marketable securities and restricted cash at March 31, 2022 totaled $389.1 million compared to $403.2 million as of December 31, 2021. LianBio projects its current cash, cash equivalents, marketable securities, and restricted cash will be sufficient to fund its current operating plan through mid-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, inflammatory disease and respiratory 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 additional information, please visit the company's website at 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," "continue," "expect," "potential," "project," "target," 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, the advancement of its pipeline of therapeutic candidates, its ability to bring transformative medicines to patients across Asia, the availability of new in-licensing opportunities, and the timeline through which it expects to be able to fund its operating expenses and capital expenditure requirements, as well as statements regarding our 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 139,857	$ 228,182
Marketable securities	229,278	155,067
Related party receivable	2,062	—
Prepaid expenses and other current assets	8,973	10,354
Other receivable	5,966	6,044
Total current assets	386,136	399,647
Restricted cash, non-current	20,000	20,000
Property and equipment, net	2,923	1,882
Operating lease right-of-use assets	4,370	4,763
Other non-current assets	50	51
Total assets	$ 413,479	$ 426,343
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 7,927	$ 3,231
Accrued expenses	14,874	9,976
Current portion of operating lease liabilities	1,374	1,125
Other current liabilities	979	760
Total current liabilities	25,154	15,092
Operating lease liabilities	3,345	3,709

Other liabilities	207	206
Nonrefundable research deposit	20,000	20,000
Total liabilities	48,706	39,007
Commitments and contingencies (Note 8)		
Shareholders' equity (deficit):		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of March 31, 2022; 107,275,458 shares issued and outstanding at March 31, 2022; Authorized 2,923,900,005 shares as of December 31, 2021; 107,275,458 shares issued and outstanding at December 31, 2021	2	2
Additional paid-in capital	719,648	713,269
Accumulated other comprehensive (loss) income	(690)	526
Accumulated deficit	(387,961)	(360,235)
Total LianBio shareholders' equity	330,999	353,562
Non-controlling interest	33,774	33,774
Total shareholders' equity	364,773	387,336
Total liabilities and shareholders' equity	$ 413,479	$ 426,343

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2022
Operating expenses:		
Research and development	$ 12,329	$ 53,353
General and administrative	16,088	7,146
Total operating expenses	28,417	60,499
Loss from operations	(28,417)	(60,499)
Other income (expense):		
Interest income	280	33
Other income (expense), net	417	(124)
Net loss before income taxes	(27,720)	(60,590)
Income taxes	6	975
Net loss	(27,726)	(61,565)
Other comprehensive (loss) income:		
Foreign currency translation (loss) income, net of tax	(393)	8
Unrealized loss on marketable securities, net of tax	(823)	—
Comprehensive loss	$ (28,942)	$ (61,557)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.26)	$ (3.01)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	107,275,458	20,477,338