LianBio Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

March 30, 2022

Phase 3 registrational trial of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) ongoing

Mavacamten granted breakthrough therapy designation in China for the treatment of patients with oHCM

Infigratinib approved under special named patient program for the treatment of cholangiocarcinoma (CCA) in the Bo'Ao pilot zone of Hainan Province in China

Three additional pipeline programs expected to enter into registrational Phase 3 clinical trials in China by year-end 2022

Cash balance of $403.2 million with runway through 2023

SHANGHAI and PRINCETON, N.J., March 30, 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 fourth quarter and year ended December 31, 2021.

“We are proud of our progress over the past year, highlighted by the achievement of key clinical and corporate milestones, including the initiation of the Phase 3 EXPLORER-CN trial of mavacamten in Chinese patients with symptomatic oHCM, and the approval of infigratinib for the treatment of cholangiocarcinoma patients in the Hainan Province in China,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “LianBio continues to advance our pipeline of clinically validated therapeutic candidates and we plan to initiate pivotal studies of three additional programs, TP-03, NBTXR3 and infigratinib, in China by year-end. We remain focused on our cross-border development strategy and are committed to building our pipeline of novel medicines for patients in Greater China and other Asian markets.”

Recent Business Highlights and Clinical Development Updates

Phase 3 EXPLORER-CN trial of mavacamten in symptomatic oHCM patients initiated and PK trial dosing completed

- In November 2021, LianBio initiated and completed enrollment and dosing in a pharmacokinetic (PK) study of mavacamten in healthy Chinese volunteers.
- In January 2022, LianBio initiated the Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with symptomatic oHCM.
- In February 2022, LianBio's partner Bristol Myers Squibb (BMS) announced positive topline results from the Phase 3 VALOR-HCM trial, evaluating mavacamten in patients with oHCM who are eligible for septal reduction therapy.
- In February 2022, LianBio announced that 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.

Infigratinib approved for the treatment of CCA in the Bo'ao pilot zone of Hainan Province

- In December 2021, infigratinib received approval from the Health Commission and Medical Products Administration of Hainan Province, under the special Named Patient Program (NPP), for the treatment of patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement. The approval enables early commercial access to infigratinib in the Bo’ao Lecheng International Medical Tourism Pilot Zone based on the drug’s approval in other global jurisdictions.

Expanded leadership team with key executive hires and named two additions to board of directors

- In October 2021, LianBio named Michael Humphries, MBBS, as Chief Scientific Advisor to guide research and development (R&D) strategy, advance the pipeline, and lead assessment of new in-licensing opportunities.
- In October 2021, LianBio appointed Jesse Wu and Susan Silbermann to the Board of Directors.

Raised $334.5 million of gross proceeds from IPO

- In November 2021, LianBio raised gross proceeds of $334.5 million and aggregate net proceeds of $304.8 million in connection with its initial public offering and subsequent exercise of the underwriters’ option to purchase additional ADSs.

Key Anticipated Milestones Expected in 2022

Mavacamten
BMS-partnered cardiac myosin inhibitor in development for the treatment of hypertrophic cardiomyopathy and certain forms of heart failure

- LianBio's partner BMS has announced a Prescription Drug User Fee Act (PDUFA) target action date of April 28, 2022 for its New Drug Application to the U.S. Food and Drug Administration (FDA) for mavacamten for the treatment of patients with oHCM.

TP-03
Tarsus Pharmaceuticals-partnered GABA-Cl channel blocker in development for the treatment of Demodex blepharitis (DB) and meibomian gland disease

- LianBio expects to initiate a Phase 3 trial of TP-03 in Chinese patients with DB in the second half of 2022 to support regulatory approval in China.
- LianBio's partner Tarsus has announced that it expects to report topline data in April 2022 from the ongoing Phase 3 Saturn-2 trial of TP-03 in DB patients.

NBTXR3
Nanobiotix-partnered radioenhancer in development for multiple solid tumor indications

- LianBio expects to begin dosing Chinese patients in Nanobiotix's ongoing global pivotal Phase 3 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

QED-partnered FGFR1-3 inhibitor in development for the treatment of individuals with FGFR-driven cancers

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

Fourth Quarter and Full-Year 2021 Financial Results:

Research & Development Expenses

R&D Expenses: Research and development expenses were $7.7 million for the fourth quarter of 2021 compared to $2.7 million for the fourth quarter of 2020, and $158.7 million for the year ended December 31, 2021 compared to $120.9 million for the year ended December 31, 2020. The increase was primarily attributable to increased milestone payments and development activities to support clinical trials and personnel-related expenses (including share-based compensation expense) as a result
of increased employee headcount, development activities to support our clinical trials and professional
fees.

General & Administrative Expenses

G&A Expenses: General and administrative expenses were $14.4 million for the fourth quarter of 2021 compared to $6.5 million for the fourth quarter of 2020, and $36.9 million for the year ended December 31, 2021 compared to $14.0 million for the year ended December 31, 2020. The increase was primarily attributable to increases in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and increases in legal service costs, consulting costs and accounting services.

Net Loss

Net Loss: Net loss was $21.2 million for the fourth quarter of 2021 compared to net loss of $12.7 million for the fourth quarter of 2020, and $196.3 million for the year ended December 31, 2021 compared to $139.6 million for the year ended December 31, 2020.

Cash Balance

Cash balance: Cash, cash equivalents, marketable securities, and restricted cash at December 31, 2021 totaled $403.2 million, reflecting a net increase of $148.9 million from December 31, 2020. LianBio projects its cash position is sufficient to fund current operations through 2023.

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.

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," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" 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 final prospectus for its initial public offering dated October 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.

For investor inquiries, please contact:
IR@lianbio.com

For media inquiries, please contact:
katherine.smith@canalecomm.com

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 228,182	$ 254,350
Marketable securities	155,067	—
Prepaid expenses and other current assets	10,354	2,396
Other receivable	6,044	20,000
Total current assets	399,647	276,746
Restricted cash, non-current	20,000	—
Property and equipment, net	1,882	822
Operating lease right-of-use assets	4,763	1,706
Other non-current assets	51	12
Total assets	$ 426,343	$ 279,286
Liabilities, Redeemable Convertible Preferred Shares and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,231	$ 4,329
Accrued expenses	9,976	998
Current portion of operating lease liabilities	1,125	539
Other current liabilities	760	360
Total current liabilities	15,092	6,226
Operating lease liabilities	3,709	1,341
Other liabilities	206	—
Nonrefundable research deposit	20,000	20,000
Total liabilities	39,007	27,567
Commitments and contingencies (Note 8)		
Redeemable convertible preferred shares, $0.0001 par value. No shares authorized, issued and outstanding at December 31, 2021; 10,971,231 shares authorized, issued, and outstanding as of December 31, 2020	—	349,789
Shareholders' equity (deficit):		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of December 31, 2021; 107,275,458 shares issued and outstanding at December 31, 2021; Authorized 2,859,742,435 shares as of December 31, 2020; 20,477,338 shares issued and outstanding at December 31, 2020	2	—
Additional paid-in capital	713,269	31,132
Accumulated other comprehensive income (loss)	526	(40)
Accumulated deficit	(360,235)	(163,935)
Total LianBio shareholders' equity (deficit)	353,562	(132,843)
Non-controlling interest	33,774	34,773

Total shareholders' equity (deficit)	387,336	(98,070)
Total liabilities, redeemable convertible preferred shares and shareholders' equity (deficit)	$ 426,343	$ 279,286

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

	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating expenses:				
Research and development	7,653	2,712	158,692	120,885
General and administrative	14,383	6,492	36,878	13,984
Total operating expenses	22,036	9,204	195,570	134,869
Loss from operations	(22,036)	(9,204)	(195,570)	(134,869)
Other income (expense):				
Interest income (expense), net	72	(3,574)	243	(4,854)
Other (expense) income, net	(265)	42	(455)	123
Net loss before income taxes	(22,230)	(12,736)	(195,782)	(139,600)
Income taxes (benefit) expense	(1,035)	—	518	4
Net loss	(21,195)	(12,736)	(196,300)	(139,604)
Other comprehensive income (loss):				
Foreign currency translation income (loss), net of tax	408	25	512	(40)
Unrealized gain on marketable securities, net of tax	54	—	54	—
Comprehensive loss	$ (20,733)	$ (12,711)	$ (195,734)	$ (139,644)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.28)	$ (0.73)	$ (5.71)	$ (11.58)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	75,479,076	17,369,481	34,394,622	12,051,433