LianBio Provides Corporate Update and Reports Third Quarter 2021 Financial Results

December 9, 2021

Initiated and completed dosing in pharmacokinetic (PK) study of mavacamten in healthy Chinese volunteers

Initiated Phase 2a clinical trial of infigratinib in Chinese patients with gastric cancer and other advanced solid tumors

Strengthened leadership team with appointment of scientific and commercial executives

Completed initial public offering for gross proceeds of approximately $334.5 million, providing cash runway through 2023

SHANGHAI, China and PRINCETON, N.J., Dec. 09, 2021 (GLOBE NEWSWIRE) -- LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today provided a corporate update and reported financial results for the third quarter ended September 30, 2021.

“Over the past several months, the LianBio team has achieved multiple meaningful milestones, including initiating our first clinical trial, completing dosing in our first PK study and successfully completing our initial public offering,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “In the year ahead, we intend to continue to advance our pipeline of innovative medicines and expect to initiate four pivotal studies to support regulatory approval in our territories. I’m confident we have the leadership and expertise at hand, as well as the capital resources necessary to deliver on our commitment to bring transformative medicines to patients across Asia.”

Recent Business Highlights and Clinical Development Updates:

Initiated and completed enrollment and dosing in pharmacokinetic study of mavacamten

- In November, LianBio initiated and completed enrollment and dosing in a pharmacokinetic (PK) study of mavacamten in healthy Chinese volunteers.

Initiated Phase 2a clinical trial of infigratinib in gastric cancer and other advanced solid tumors

- In August, LianBio announced that the first patient was dosed in a 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.

Appointed two independent directors to LianBio Board of Directors

- In October, LianBio appointed Jesse Wu to the Company’s Board of Directors. Mr. Wu is the former Chairman of Johnson & Johnson China.

- In October, LianBio appointed Susan Silbermann to the Company’s Board of Directors. Ms. Silbermann is the former Global President, Emerging Markets at Pfizer.

Strengthened LianBio leadership team with key China-based hires

- In October, LianBio appointed Michael Humphries, MBBS as Chief Scientific Advisor to guide the Company’s research and development (R&D) strategy, advance the Company’s pipeline, and lead assessment of new in-licensing opportunities.

- In August, LianBio appointed Pascal Qian as China General Manager to build out the Company’s operations and commercial infrastructure.

Completed Initial Public Offering

- In November, LianBio completed an initial public offering (IPO) of its ordinary shares through the sale and issuance of 20,312,500 American Depositary Shares (ADSs) at a public offering price of $16.00 per ADS. Following the close of the IPO, pursuant to the partial exercise of their option to purchase additional ADSs, the underwriters purchased an additional 593,616 ADSs at the IPO price of $16.00 per ADS.

- LianBio received gross proceeds of $334.5 million in connection with the IPO and subsequent exercise of the underwriters’ option and aggregate net proceeds of $311.1 million after deducting underwriting discounts and commissions.

2022 Key Anticipated Milestones

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

- LianBio expects to initiate the Phase 3 EXPLORER-CN trial of mavacamten in Chinese patients with obstructive hypertrophic cardiomyopathy in the first quarter of 2022 to support regulatory approval in China.
- LianBio's partner BMS has announced a Prescription Drug User Fee Act (PDUFA) target action date of April 28, 2022 for the Company's New Drug Application to the U.S. Food and Drug Administration (FDA) for mavacamten for the treatment of patients with symptomatic obstructive hypertrophic cardiomyopathy (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 the Company expects to report topline data in the first quarter of 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 planned 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.

LYR-210
Lyra Therapeutics-partnered anti-inflammatory implantable drug matrix in development for the treatment of surgically-naïve, medically refractory chronic rhinosinusitis

- LianBio expects to begin dosing Chinese patients in Lyra's planned global pivotal Phase 3 trial of LYR-210 for the treatment of surgically naïve chronic rhinosinusitis in the second half of 2022.

Third Quarter 2021 Financial Results:

Research & Development Expenses

R&D expenses were $4.7 million for the three months ended September 30, 2021, as compared to $116.9 million for the three months ended September 30, 2020. For the three months ended September 30, 2021, research and development cost was primarily attributable to $1.9 million in personnel-related expenses and $2.1 million in professional fees for development activities to support clinical trials.

General & Administrative Expenses

G&A expenses were $8.9 million for the three months ended September 30, 2021, as compared to $2.1 million for the three months ended September 30, 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 was $13.1 million for the three months ended September 30, 2021, or a net loss per share of $0.63, as compared to a net loss of $120.2 million for the three months ended September 30, 2020, or a net loss per share of $11.71.

Cash and Cash Equivalents

Cash and cash equivalents were $109.0 million as of September 30, 2021, which excludes the net proceeds of $311.1 million from the Company's initial public offering, as compared to $254.4 million as of December 31, 2020. The Company expects its current cash and cash equivalents, inclusive of the IPO net proceeds subsequently received in November 2021, will be sufficient to fund its operating expenses and capital expenditure requirements 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.

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Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Operating expenses:				
Research and development	$ 4,655	$ 116,915	$ 151,038	$ 118,173
General and administrative	8,889	2,129	22,496	7,492
Total operating expenses	13,544	119,044	173,534	125,665
Operating loss	(13,544)	(119,044)	(173,534)	(125,665)
Other income (expense):				
Interest income (expense), net	32	(1,293)	171	(1,280)
Other income (expense), net	3	99	(189)	81
Net loss before income taxes	(13,509)	(120,238)	(173,552)	(126,864)
Income tax (benefit) expense	(397)	—	1,553	2
Net loss	(13,112)	(120,238)	(175,105)	(126,866)
Other comprehensive (loss) income:				
Foreign currency translation (loss) income, net of tax	(26)	(3)	104	(56)
Comprehensive loss	$ (13,138)	$ (120,241)	$ (175,001)	$ (126,922)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.63)	$ (11.71)	$ (8.52)	$ (12.36)

Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	20,690,908	10,265,811	20,549,310	10,265,811

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 109,015	$ 254,350
Prepaid expenses and other current assets	6,204	2,396
Other receivable	5,784	20,000
Total current assets	121,003	276,746
Restricted cash, non-current	20,000	—
Property and equipment, net	707	822
Operating lease right-of-use assets	206	1,706
Other non-current assets	10	12
Total assets	$ 141,926	$ 279,286
Liabilities, Redeemable Convertible Preferred Shares and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,639	$ 4,329
Accrued expenses	12,630	998
Current portion of operating lease liabilities	306	539
Withholding tax payable	5,957	—
Other current liabilities	1,727	360
Total current liabilities	22,259	6,226
Operating lease liabilities	—	1,341
Nonrefundable research deposit	20,000	20,000
Total liabilities	42,259	27,567
Commitments and contingencies		
Redeemable convertible preferred shares, $0.0001 par value. Authorized 11,024,178 and 10,971,231 shares as of September 30, 2021 and December 31, 2020, respectively; 11,024,178 and 10,971,231 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	352,729	349,789
Shareholders' deficit:		
Ordinary shares, $0.000017100448 par value. Authorized 2,859,432,812 shares as of September 30, 2021; 21,787,245 shares issued and outstanding at September 30, 2021; Authorized 2,859,742,435 shares as of December 31, 2020; 20,477,338 shares issued and outstanding at December 31, 2020	—	—
Additional paid-in capital	41,726	31,132
Accumulated other comprehensive income (loss)	64	(40)
Accumulated deficit	(339,040)	(163,935)
Total LianBio shareholders' deficit	(297,250)	(132,843)
Non-controlling interest	44,188	34,773
Total shareholders' deficit	(253,062)	(98,070)
Total liabilities, redeemable convertible preferred shares and shareholders' deficit	$ 141,926	$ 279,286