UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 13, 2023

LIANBIO

(Exact name of registrant as specified in its charter)

Cayman Islands	**001-40947**	**98-1594670**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

103 Carnegie Center Drive, Suite 309 **Princeton, NJ**	**08540**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (609) 486-2308

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American depositary shares, each representing 1 ordinary share, $0.000017100448 par value per share	**LIAN**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2023, LianBio (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by LianBio, dated November 13, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LIANBIO

By: /s/ Yizhe Wang

Yizhe Wang

Chief Executive Officer

Date: November 13, 2023

LianBio Reports Third Quarter 2023 Financial Results and Provides Corporate Update

- *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., November 13, 2023 – 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,” “continue,” “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 LianBio Board of Directors' comprehensive strategic review; LianBio's plans to discuss the data from the Phase 3 LIBRA trial of TP-03 with the NMPA and to use these data to support a New Drug Application in China; the advancement of its pipeline of therapeutic candidates; its ability to bring transformative medicines to patients in China and across Asia; and the timeline through which it expects to be able to fund its operating expenses and capital expenditure requirements. 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