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): March 27, 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):

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

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

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

☐ 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 ☒

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. ☒

Item 2.02 Results of Operations and Financial Condition.

On March 27, 2023, LianBio issued a press release announcing its financial results for the year ended December 31, 2022. 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 March 27, 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: March 27, 2023

LianBio Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

Phase 3 trial of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) ongoing, with data expected mid-year 2023

Phase 3 registrational trial of TP-03 in Chinese patients with Demodex blepharitis ongoing, with data expected in the fourth quarter of 2023

Entered into commercial agreement with Pfizer, with Pfizer opting into LianBio rights to RSV therapeutic candidate sisunatovir in LianBio territories

Cash, cash equivalents and marketable securities of $302.4 million with runway through the end of 2024

Shanghai and Princeton, N.J., March 27, 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 fourth quarter and year ended December 31, 2022.

“2022 marked a pivotal year for LianBio, with sustained progress across our pipeline and building of our commercial infrastructure in anticipation of registration of mavacamten in China,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "This year, we look forward to pivotal data in the EXPLORER-CN trial of mavacamten and the LIBRA trial of TP-03, and to filing the mavacamten NDA in China. With a cash runway through the end of 2024, we believe LianBio is well positioned to become a commercial-stage company. Looking ahead, we are excited to continue advancing our mission to bring innovative medicines to patients in Asia.”

Recent Business Highlights and Clinical Development Updates

Mavacamten late-stage clinical development and launch readiness activities on track in China; New Drug Applications now on file in Singapore, Hong Kong and Macau

- In March 2023, patient visits in the double-blinded placebo-controlled treatment period were completed in the Phase 3 EXPLORER-CN study of mavacamten in Chinese symptomatic oHCM patients.
- In February 2023, LianBio submitted an NDA for mavacamten for the treatment of adults with symptomatic New York Heart Association Class II-III obstructive hypertrophic cardiomyopathy (oHCM) in the Macau Special Administrative Region. The submission was based on the U.S. Food and Drug Administration (FDA) approval of mavacamten. LianBio has now filed New Drug Applications to support approval of mavacamten in Hong Kong, Singapore and Macau.
- 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.

- LianBio continues to hire key leadership roles to support the expected mavacamten commercial launch in China, including sales and marketing, market access, distribution, and medical affairs personnel.
- LianBio continues to work with the physician community and academic societies in China to drive disease awareness and improve the standardization of diagnosis and treatment of HCM.

Registrational Phase 3 LIBRA clinical trial of TP-03 for the treatment of Demodex blepharitis initiated in China

- In November 2022, LianBio announced the initiation of the Phase 3 LIBRA clinical trial of TP-03 in Demodex blepharitis. LianBio expects the LIBRA trial to support TP-03 registration in China.

Phase 1 clinical trial of BBP-398 SHP2 inhibitor initiated in China

- In November 2022, LianBio announced the initiation of a Phase 1 monotherapy dose escalation trial of BBP-398 in Chinese patients with advanced solid tumors.

Entered into commercial agreement with Pfizer for the development and commercialization of sisunatovir

- In December 2022, LianBio entered into a commercial agreement with Pfizer and ReViral Ltd., now a wholly owned subsidiary of Pfizer, with respect to sisunatovir as the first opted-in product under LianBio's existing strategic collaboration with Pfizer. Pursuant to the commercial agreement, LianBio assigned and transferred development and commercialization rights to sisunatovir in Mainland China, Hong Kong, Macau and Singapore to Pfizer. LianBio received a $20.0 million upfront payment, which was released as part of previously restricted cash paid to LianBio by Pfizer in 2020 pursuant to the Pfizer strategic collaboration agreement. LianBio is eligible to receive up to $135.0 million in potential development and sales milestones. LianBio is further entitled to receive tiered payments in the low single digits on a percentage of net sales of sisunatovir in the territory. Pfizer will assume all development and commercial activities and costs in the region and will release LianBio from its royalty and milestone obligations for sisunatovir.

Business is well-positioned to achieve anticipated milestones

- Current cash runway is projected to extend through the end of 2024.

<u>Key Milestones Anticipated in 2023</u>

Mavacamten

- LianBio expects to report topline data from the Phase 3 EXPLORER-CN trial of mavacamten in Chinese patients with symptomatic oHCM in mid-2023.
- LianBio expects to file a New Drug Application (NDA) in 2023 to support regulatory approval of mavacamten in China.

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.

Fourth Quarter and Full-Year 2022 Financial Results:

Research & Development Expenses

Research and development expenses were $10.6 million for the fourth quarter of 2022 compared to $7.7 million for the fourth quarter of 2021, and $59.8 million for the year ended December 31, 2022 compared to $158.7 million for the year ended December 31, 2021. The decrease was primarily attributable to decreased milestone and upfront licensing payments. These decreases were partially offset by increases in 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

General and administrative expenses were $18.7 million for the fourth quarter of 2022 compared to $14.4 million for the fourth quarter of 2021, and $65.6 million for the year ended December 31, 2022 compared to $36.9 million for the year ended December 31, 2021. 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 $18.3 million for the fourth quarter of 2022 compared to net loss of $21.2 million for the fourth quarter of 2021, and $110.3 million for the year ended December 31, 2022 compared to $196.3 million for the year ended December 31, 2021.

Cash Balance

Cash, cash equivalents and marketable securities at December 31, 2022 totaled $302.4 million, reflecting a net decrease of $100.8 million from December 31, 2021. LianBio projects its cash position is sufficient to fund current operations through the end of 2024.

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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,” “believe,” “continue,” “estimate,” “potential,” “expect,” “may,” 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 becoming a commercial-stage company, the Company’s expectations in 2023 with regards to filing the mavacamten NDA to support the registration of mavacamten in China and its plans to initiate a clinical trial for BBP-398 as well as its plans to initiate a Phase 2 trial of infigratinib in 2024, the Company’s efforts to build out its commercial infrastructure related to mavacamten, the Company’s plans and expectations with respect to its ability to develop and bring TP-03 and its other product candidates to patients in China such as the potential for the LIBRA trial to support registration of TP-03 in China, and the Company’s plans and expectations with respect to the timing of initiation, completion and reporting of topline data from the EXPLORER-CN trial of mavacamten, the LIBRA trial of TP-03, the Phase 2a clinical trial of infigratinib as well as results from its planned and ongoing clinical trials in China and its other licensed territories. 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 filed with the SEC on March 31, 2022 and subsequent filings with the SEC including, when available, the Annual Report on Form 10-K for the year ended December 31, 2022. 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:
Elizabeth Anderson, VP Communications and Investor Relations
E: elizabeth.anderson@lianbio.com
T: +1 646 655 8390

For media inquiries, please contact:
Josh Xu, Director of Communications
E: josh.xu@lianbio.com
T: +86 136 6140 8315

Katherine Smith, Evoke Canale
E: katherine.smith@evokegroup.com
T: +1 619 849 5378

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 79,221	$ 228,182
Marketable securities	223,142	155,067
Prepaid expenses and other current assets	8,640	10,354
Other receivable	1,770	6,044
Total current assets	312,773	399,647
Restricted cash, non-current	73	20,000
Property and equipment, net	3,116	1,882
Operating lease right-of-use assets	3,978	4,763
Other non-current assets	20	51
Total assets	$ 319,960	$ 426,343
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,453	$ 3,231
Accrued expenses	19,826	9,976
Current portion of operating lease liabilities	1,851	1,125
Other current liabilities	485	760
Total current liabilities	23,615	15,092
Operating lease liabilities	2,488	3,709
Other liabilities	210	206
Nonrefundable research deposit	—	20,000
Total liabilities	26,313	39,007
Commitments and contingencies (Note 8)		
Shareholders' equity (deficit):		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of December 31, 2022; 107,043,924 shares issued and outstanding at December 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	732,476	713,269
Accumulated other comprehensive (loss) income	(2,080)	526
Accumulated deficit	(470,525)	(360,235)
Total LianBio shareholders' equity	259,873	353,562
Non-controlling interest	33,774	33,774
Total shareholders' equity	293,647	387,336
Total liabilities and shareholders' equity	$ 319,960	$ 426,343

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

	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating expenses:				
Research and development	$ 10,577	$ 7,653	$ 59,755	$ 158,692
General and administrative	18,668	14,383	65,598	36,878
Total operating expenses	29,245	22,036	125,353	195,570
Loss from operations	(29,245)	(22,036)	(125,353)	(195,570)
Other income (expense):				
Interest income, net	2,083	72	4,321	243
Other income (expense), net	8,536	(265)	10,409	(455)
Net loss before income taxes	(18,626)	(22,229)	(110,623)	(195,782)
Income tax (benefit) expenses	(350)	(1,035)	(333)	518
Net loss	(18,276)	(21,194)	(110,290)	(196,300)
Other comprehensive (loss) income:				
Foreign currency translation (loss) income, net of tax	1,384	408	(1,712)	512
Unrealized (loss) gain on marketable securities, net of tax	380	54	(894)	54
Comprehensive loss	$ (16,512)	$ (20,732)	$ (112,896)	$ (195,734)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.17)	$ (0.28)	$ (1.02)	$ (5.71)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	108,127,303	75,479,076	107,923,296	34,394,622