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): April 26, 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 7.01. Regulation FD Disclosure.

On April 26, 2023, LianBio (the "Company") issued a press release announcing topline results from its Phase 3 EXPLORER-CN trial investigating mavacamten for the treatment of Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy ("oHCM"), a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. The Company intends to host a virtual event for analysts and investors to discuss the topline data from EXPLORER-CN and an overview of the China market opportunity for mavacamten, pending regulatory approval, at 8:00 a.m. EDT / 8:00 p.m. CST on May 1, 2023.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it 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 8.01 Other Events.

On April 26, 2023, the Company announced topline results from its Phase 3 EXPLORER-CN trial investigating mavacamten for the treatment of Chinese patients with symptomatic oHCM.

EXPLORER-CN met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in Valsalva left ventricular outflow tract ("LVOT") gradient from baseline to week 30 compared to placebo ($p<0.001$). Additionally, mavacamten demonstrated improvement for all secondary endpoints, including change from baseline to week 30 in resting LVOT peak gradient, proportion of participants achieving a Valsalva LVOT peak gradient <30 mmHg at week 30, proportion of participants achieving a Valsalva LVOT peak gradient <50 mmHg at week 30, proportion of participants with at least one NYHA class improvement from baseline to week 30, change from baseline to week 30 in Kansas City Cardiomyopathy Questionnaire ("KCCQ") Clinical Summary Score ("CSS"), and change from baseline to week 30 in left ventricular mass index evaluated by cardiac magnetic resonance imaging.

Safety results in the trial were consistent with previous studies of mavacamten in symptomatic oHCM, and no new safety signals were reported. No participants in the study experienced decreases in left ventricular ejection fraction ("LVEF") <50 % that required dose interruption.

The Phase 3 EXPLORER-CN trial enrolled a total of 81 patients in China with symptomatic (NYHA Class II or III) oHCM. All participants had one measurable LVOT gradient (resting or Valsalva) $\geq$50 mmHg during screening.

In April 2023, the China National Medical Products Administration ("NMPA") accepted with Priority Review a New Drug Application ("NDA") for mavacamten for the treatment of adults with symptomatic oHCM. The NDA is based on data from the global pivotal Phase 3 EXPLORER-HCM trial, which evaluated the safety and efficacy of mavacamten in patients with symptomatic oHCM compared to placebo. Results from the EXPLORER-HCM trial showed that mavacamten demonstrated a robust treatment effect, with clinically meaningful improvements in exercise capacity, functional status, and patient-reported outcomes, as well as the ability to relieve left ventricular outflow tract obstruction. The EXPLORER-HCM trial met all primary and secondary endpoints with statistical significance. The NDA also includes clinical data from the Company's Phase 1 pharmacokinetic study of mavacamten in healthy Chinese volunteers that demonstrated a favorable safety and tolerability profile, and a pharmacokinetic profile comparable to that observed in the Phase 1 pharmacokinetic studies of mavacamten conducted in the United States. Blinded preliminary safety data from EXPLORER-CN also supported the early NDA filing.

The Company will complete a full evaluation of the EXPLORER-CN data and expects to work with investigators to present detailed results at an upcoming medical meeting.

Cautionary Note Regarding Forward-Looking Statements

Statements in this Current Report on Form 8-K 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 "expect," "believe," "continue," "estimate," "potential," "will" 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 Current Report on Form 8-K include, but are not limited to, statements regarding the Company's plans to use the data from EXPLORER-CN and its pharmacokinetics study to support registration of mavacamten in China, including its plans

to complete a full evaluation of the EXPLORER-CN data and its expectation that it will work with investigators to present detailed results at an upcoming medical meeting. 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 the Company's filings with the U.S. Securities and Exchange Commission ("SEC"), including the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings with the SEC.

In addition, topline and interim data from clinical trials may not be indicative of final results, and the results of early clinical trials may not be indicative of the results of later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the NMPA or similar regulatory authorities in other jurisdictions, or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available.

Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by LianBio, dated April 26, 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: April 26, 2023

LianBio Announces Positive Topline Results from Phase 3 EXPLORER-CN Trial Evaluating Mavacamten in Chinese Patients

- *Mavacamten met the primary endpoint for the treatment of Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy*

- *Mavacamten demonstrated a safety profile consistent with previous studies*

- *If approved, mavacamten is expected to be the first cardiac myosin inhibitor approved in China for the treatment of oHCM*

- *LianBio to host a live virtual analyst and investor event to review EXPLORER-CN topline data and the China market opportunity for mavacamten on Monday, May 1 at 8:00 a.m. EDT / 8:00 p.m. CST*

Shanghai and Princeton, NJ, April 26, 2023 – LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today announced positive topline results from the Phase 3 EXPLORER-CN trial investigating mavacamten for the treatment of Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM).

EXPLORER-CN met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in Valsalva left ventricular outflow tract (LVOT) gradient from baseline to week 30 compared to placebo ($p<0.001$). Additionally, mavacamten demonstrated improvement for all secondary endpoints, including change from baseline to week 30 in resting LVOT peak gradient, proportion of participants achieving a Valsalva LVOT peak gradient <30 mmHg at week 30, proportion of participants achieving a Valsalva LVOT peak gradient <50 mmHg at week 30, proportion of participants with at least one NYHA class improvement from baseline to week 30, change from baseline to week 30 in Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score (CSS), and change from baseline to week 30 in left ventricular mass index evaluated by cardiac magnetic resonance imaging.

Safety results in the trial were consistent with previous studies of mavacamten in symptomatic oHCM, and no new safety signals were reported. No participants in the study experienced decreases in left ventricular ejection fraction (LVEF) <50 % that required dose interruption.

The Phase 3 EXPLORER-CN trial enrolled a total of 81 patients in China with symptomatic (NYHA Class II or III) oHCM. All participants had one measurable LVOT gradient (resting or Valsalva) $\geq$50 mmHg during screening.

“For decades, physicians have been utilizing medicines to try to manage only the symptoms of hypertrophic cardiomyopathy,” said Shuyang Zhang, M.D., Ph.D., Professor of Cardiology and President,

Peking Union Medical College Hospital and Principal Investigator of EXPLORER-CN. “Before mavacamten, oHCM patients had no therapeutic option that targeted the underlying pathophysiology of the disease. The topline results from EXPLORER-CN add to the body of evidence demonstrating mavacamten is an effective treatment option for patients worldwide who are living with this chronic and debilitating condition.”

In April 2023, the China National Medical Products Administration (NMPA) accepted with Priority Review a New Drug Application (NDA) for mavacamten for the treatment of adults with symptomatic oHCM. The NDA is based on data from the global pivotal Phase 3 EXPLORER-HCM trial, which evaluated the safety and efficacy of mavacamten in patients with symptomatic oHCM compared to placebo. Results from the EXPLORER-HCM trial showed that mavacamten demonstrated a robust treatment effect, with clinically meaningful improvements in exercise capacity, functional status, and patient-reported outcomes, as well as the ability to relieve left ventricular outflow tract obstruction. The EXPLORER-HCM trial met all primary and secondary endpoints with statistical significance. The NDA also includes clinical data from LianBio’s Phase 1 pharmacokinetic study of mavacamten in healthy Chinese volunteers that demonstrated a favorable safety and tolerability profile, and a pharmacokinetic profile comparable to that observed in the Phase 1 pharmacokinetic studies of mavacamten conducted in the United States. Blinded preliminary safety data from EXPLORER-CN also supported the early NDA filing.

“We believe the speed and quality with which the EXPLORER-CN trial was conducted is a testament to LianBio’s ability to accelerate patient access to innovative medicines,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “I would like to acknowledge our team’s hard work and commitment to the oHCM community and thank the EXPLORER-CN investigators and patients for their participation in this important study. With positive pivotal data now in hand and the NDA on file, we are optimistic about bringing mavacamten to market in China next year.”

LianBio will complete a full evaluation of the EXPLORER-CN data and expects to work with investigators to present detailed results at an upcoming medical meeting.

Analyst and Investor Conference Call and Live Webcast
LianBio will host a virtual event for analysts and investors to review the topline data from EXPLORER-CN and an overview of the China market opportunity for mavacamten, pending regulatory approval. The live webcast will begin at 8:00 a.m. EDT / 8:00 p.m. CST on Monday, May 1.

Listeners can access a live audio webcast of the conference call on the investor section of LianBio’s website at http://investors.Lianbio.com.

Research analysts who would like to participate in the live Q&A can register to obtain dial-in and passcode details. Participants may pre-register at any time, including up to and after the call start time.

A replay of the webcast and accompanying slides will be available on the LianBio website for 90 days following the call.

About Mavacamten
Camzyos®(mavacamten) is the first and only cardiac myosin inhibitor approved by the U.S. FDA indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive HCM to improve functional capacity and symptoms. It has also received regulatory approvals in Australia, Canada, Brazil and Switzerland. Camzyos is an allosteric and reversible inhibitor selective for cardiac myosin. Camzyos modulates the number of myosin heads that can enter “on actin” (power generating) states, thus reducing the probability of force producing (systolic) and residual (diastolic) cross-bridge formation. Excess myosin actin cross bridge formation and dysregulation of the super

relaxed state are mechanistic hallmarks of HCM. Camzyos shifts the overall myosin population towards an energy sparing, recruitable, super relaxed state. In HCM patients, myosin inhibition with Camzyos reduces dynamic LVOT obstruction and improves cardiac filling pressures.

LianBio licensed rights from MyoKardia, now a wholly owned subsidiary of Bristol Myers Squibb, in August 2020 for the development and commercialization of mavacamten in Mainland China, Hong Kong, Macau, Taiwan, Thailand and Singapore. Mavacamten was granted Breakthrough Therapy Designation in China for the treatment of patients with oHCM in February 2022.

About EXPLORER-HCM
The EXPLORER-HCM Phase 3 trial enrolled a total of 251 patients with symptomatic (NYHA Class II or III) oHCM. All participants had one measurable LVOT gradient (resting or provoked) $\geq$50 mmHg during screening.

The primary endpoint for EXPLORER-HCM was a composite functional analysis designed to capture mavacamten's effect on both symptoms and function. Secondary endpoints were changes from baseline to week 30 in postexercise LVOT gradient, pVO_2, proportion of participants with at least one NYHA class improvement, and measures of patient-reported outcomes. Additional endpoints included changes from baseline to Week 30 in echocardiographic indices, circulating biomarkers, cardiac rhythm patterns and accelerometry.

About EXPLORER-CN
The Phase 3 EXPLORER-CN trial enrolled a total of 81 patients in China with symptomatic (NYHA Class II or III) oHCM. All participants had one measurable LVOT gradient (resting or Valsalva) $\geq$50 mmHg during screening. Patients were randomized 2:1 to mavacamten or placebo.

The primary endpoint for EXPLORER-CN is the change from baseline to week 30 in Valsalva LVOT gradient. Secondary endpoints include change from baseline to week 30 in resting LVOT peak gradient, proportion of participants achieving a Valsalva LVOT peak gradient <30 mmHg at week 30, proportion of participants achieving a Valsalva LVOT peak gradient <50 mmHg at week 30, proportion of participants with at least one NYHA class improvement from baseline to week 30, change from baseline to week 30 in Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score (CSS), change from baseline to week 30 in N-terminal pro B-type Natriuretic Peptide (NT-proBNP), change from baseline to week 30 in cardiac troponin, and change from baseline to week 30 in left ventricular mass index evaluated by cardiac magnetic resonance imaging.

About Hypertrophic Cardiomyopathy
Hypertrophic cardiomyopathy (HCM) is a chronic, progressive disease in which excessive contraction of the heart muscle and reduced ability of the left ventricle to fill can lead to the development of debilitating symptoms and cardiac dysfunction. HCM is estimated to affect one in every 500 people globally. The most frequent cause of HCM is mutations in the heart muscle proteins of the sarcomere. In patients with both obstructive and non-obstructive HCM, exertion can result in fatigue or shortness of breath, interfering with a patient's ability to participate in activities of daily living. HCM has also been associated with increased risks of atrial fibrillation, stroke, heart failure and sudden cardiac death.

In China, there are an estimated 1.1 million to 2.8 million patients with HCM.

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.

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