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 21, 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 8.01 Other Events.

On April 21, 2023, LianBio (the "Company") issued a press release announcing that China's National Medical Products Administration has accepted with priority review the New Drug Application for mavacamten for the treatment of symptomatic obstructive hypertrophic cardiomyopathy in adults. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by LianBio, dated April 21, 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 21, 2023

LianBio Announces China National Medical Products Administration (NMPA) Acceptance with Priority Review of New Drug Application for Mavacamten for the Treatment of Patients with Obstructive Hypertrophic Cardiomyopathy

Shanghai and Princeton, NJ, April 21, 2023 – LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today announced that China's National Medical Products Administration (NMPA) has accepted with priority review the New Drug Application (NDA) for mavacamten for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adults.

"We are one step closer to bringing mavacamten to patients with obstructive HCM in China as a first-in-class, clinically validated treatment option," said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "Gaining alignment with the NMPA to file the NDA prior to the completion of our ongoing Phase 3 trial in China speaks to the strength of the clinical data that has been generated and to our commitment to accelerate patient access to critical new treatments. This is a pivotal moment for LianBio as we prepare to transform into a commercial-stage company, and we believe is a great testament to our ability to navigate evolving regulatory and clinical development pathways in China."

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 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. More information about the EXPLORER-HCM trial can be found on ClinicalTrials.gov (NCT03470545).

The NDA also includes clinical data from LianBio's Phase 1 pharmacokinetic study of mavacamten in healthy Chinese volunteers. This study demonstrated a safety and tolerability profile, and a pharmacokinetic profile comparable to those observed in the Phase 1 pharmacokinetic studies of mavacamten conducted in the United States. Blinded preliminary safety data from LianBio's ongoing Phase 3 EXPLORER-CN trial of mavacamten in Chinese patients with symptomatic oHCM also supported the early NDA filing. Topline data from this study are expected mid-2023. More information about the pharmacokinetic study of mavacamten and the EXPLORER-CN trial can be found on ClinicalTrials.gov (NCT05135871 and NCT05174416, respectively).

"HCM significantly impacts patients' quality of life. Currently, there is a lack of effective treatment options and innovative drugs are urgently needed for clinical use," said Shuyang Zhang, M.D., Ph.D., Professor of Cardiology and President, Peking Union Medical College Hospital, and Principal Investigator, EXPLORER-CN. "As the first therapy that targets the pathophysiology of disease, mavacamten holds the potential to improve treatment of oHCM in China and positively impact patients' health and ability to perform tasks of daily living. "

About Camzyos (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 and Brazil. 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 left ventricular outflow tract (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 Phase 3 EXPLORER-HCM trial enrolled a total of 251 patients with symptomatic (NYHA Class II or III), obstructive hypertrophic cardiomyopathy. All participants had measurable left ventricular outflow tract (LVOT) gradient (resting and/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), obstructive hypertrophic cardiomyopathy. All participants had measurable left ventricular outflow tract (LVOT) gradient (resting and/or provoked) $\geq$50 mmHg during screening.

The primary endpoint for EXPLORER-CN is the change from baseline to week 30 in Valsalva LVOT gradient. Secondary endpoints include changes from baseline to week 30 in LVOT obstruction, proportion of participants with at least one NYHA class improvement, measures of patient-reported outcomes, cardiac biomarkers, and left ventricular mass index. Additional endpoints include changes from baseline to Week 30 in echocardiographic and cardiac magnetic resonance parameters, proportion of participants achieving NYHA class I and resting and Valsalva LVOT gradient < 30 mmHg at week 30.

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 both obstructive and non-obstructive HCM patients, 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, we estimate there are approximately 1.1 million to 2.8 million patients with HCM, with approximately two-thirds of patients having oHCM, and one-third of patients having non-obstructive 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, 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. 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 “expect,” “estimate” and “potential” 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 regarding the Company’s plans and expectations to report topline results in mid-2023 and to use the data from EXPLORER-CN and its pharmacokinetic study to support registration of mavacamten in China; the potential impact of mavacamten on patient lives; the Company’s beliefs regarding Chinese oHCM patients’ demand for new therapies, physician and patient enthusiasm for mavacamten, and the Company’s strong clinical development capabilities in China; the Company’s ability to navigate complex regulatory environments in China; the continued growth of the Company as and transformation to a commercial-stage company; and the Company’s work with respect to its ability to develop and bring mavacamten to patients in Asia. 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.

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