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): December 16, 2022

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 1.01 Entry into a Material Definitive Agreement.

On December 16, 2022, LianBio Development HK Limited and LianBio Respiratory Limited, each a wholly-owned subsidiary of LianBio (the "Company," and collectively with LianBio Development HK Limited and LianBio Respiratory Limited, "LianBio"), Pfizer Inc. ("Pfizer") and ReViral Ltd. ("ReViral," now a wholly-owned subsidiary of Pfizer) entered into a commercial agreement (the "Commercial Agreement") with respect to sisunatovir (a fusion inhibitor product for treatment of respiratory syncytial virus (or RSV)) as the first Opted-in Product under the Strategic Collaboration Agreement dated November 17, 2020 by and between the Company and Pfizer (the "Collaboration Agreement"). Pursuant to the Commercial Agreement, LianBio will assign and transfer its development and commercialization rights to sisunatovir in Mainland China, Hong Kong, Macau and Singapore (the "Territory") to Pfizer. Capitalized terms not defined herein shall, unless otherwise indicated, have the meanings ascribed to such terms in the Collaboration Agreement or the Commercial Agreement.

Under the Commercial Agreement, LianBio will receive a $20 million upfront payment, to be released as part of previously restricted cash paid by Pfizer to LianBio in 2020 pursuant to the Collaboration Agreement. In addition, LianBio could also receive up to $135 million in potential development and sales milestones contingent on sisunatovir achieving a specified regulatory milestone event prior to the end of October 2035 and specified net sales milestone events. 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 lead all development and commercial activities, use commercially reasonable efforts to develop and seek regulatory approval for sisunatovir as a fusion inhibitor product for treatment of RSV as a single active pharmaceutical product in Mainland China, assume all costs in the Territory, and will waive LianBio's milestone payment and royalty payment obligations previously due to ReViral pursuant to the Co-Development and License Agreement dated March 1, 2021 by and between LianBio Respiratory Limited and ReViral, which was superseded in its entirety by the Commercial Agreement.

The Company believes that this transaction will extend LianBio's cash runway through the end of 2024.

Pfizer's payment obligations to LianBio under the Commercial Agreement starts from the first commercial sale of sisunatovir in the Territory until the end of October 2035. In addition, for regions where there is no valid claim covering the applicable product or any regulatory exclusivity, Pfizer's net sales payment obligations end and sales in such regions are no longer counted in the determination of the achievement of net sales milestone events. Pfizer's payment obligations may be earlier terminated for LianBio's uncured material breach or if LianBio challenges any of the licensed patents.

The foregoing description of the Commercial Agreement does not purport to be complete and is qualified in its entirety by reference to the Commercial Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the period ending on December 31, 2022.

Item 7.01 Regulation FD Disclosure.

On December 19, 2022, LianBio issued a press release announcing the entry into the Commercial Agreement. A copy of this press release is furnished herewith as Exhibit 99.1 to this report. The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the 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 Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated December 19, 2022
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: December 19, 2022

Pfizer Opts In to LianBio Rights to Respiratory Syncytial Virus Therapeutic Candidate Sisunatovir in Mainland China, Hong Kong, Macau, and Singapore

- *Pfizer will now lead all development and commercialization activities in Mainland China, Hong Kong, Macau, and Singapore*
- *LianBio will receive a $20 million upfront payment, to be released from previously restricted cash paid by Pfizer to LianBio in 2020 under the companies' existing strategic collaboration*
- *LianBio is eligible to receive up to $135 million in potential development and commercial milestone payments and tiered low single digit percent of net sales in the territories*

Shanghai, and Princeton, N.J., December 19, 2022 – Pfizer Inc. (NYSE: PFE) and LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today announced that Pfizer opted in to the right to develop and commercialize sisunatovir, a respiratory syncytial virus (RSV) therapeutic candidate, in Mainland China, Hong Kong, Macau, and Singapore pursuant to the companies' existing strategic collaboration to expand patient access to novel therapeutics in Greater China.

Sisunatovir is an investigational, orally administered fusion inhibitor designed to block RSV replication by inhibiting F-mediated fusion with the host cell. Sisunatovir is being evaluated for the potential treatment of RSV infection in pediatric and adult patients.

"Like LianBio, Pfizer recognizes the promise of sisunatovir to address significant treatment gaps for patient populations vulnerable to severe complications of RSV," said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "During typical RSV seasons, more than 400,000 pediatric and elderly patients in China are hospitalized with RSV-associated lower respiratory tract infections. Pfizer is a leader in advancing research and development for RSV vaccines and therapeutics, and their expertise studying different modalities of treatment is expected to be instrumental in bringing a new therapeutic option to as many patients in need as possible."

In June 2022, Pfizer acquired ReViral Ltd. and its portfolio of RSV therapeutic candidates with the exception of development and commercialization rights for sisunatovir in Mainland China, Hong Kong, Macau, and Singapore, which LianBio had previously in-licensed from ReViral in March 2021.

"At Pfizer, we are committed to advancing potentially critical vaccines and therapies to help address significant unmet need in infectious diseases around the world, including RSV, and we're pleased that this ongoing collaboration with LianBio has the potential to provide more patients with access to a much-needed treatment," said Jean-Christophe Pointeau, China President for Pfizer Global Biopharma Business. "We believe that, if clinically successful and approved, sisunatovir may help change the standard of care for patients with RSV disease, for whom treatment options are currently limited."
Under the terms of Pfizer's opt-in to sisunatovir rights, LianBio will receive a $20 million upfront payment, to be released from previously restricted cash paid by Pfizer to LianBio in 2020 under the companies' existing strategic collaboration. Additionally, LianBio is eligible to receive up to $135 million in potential

development and commercial milestone payments and tiered low single digit percent of sisunatovir net sales in the territories. 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.

About Sisunatovir
Sisunatovir is an investigational orally administered fusion inhibitor designed to block RSV replication by inhibiting F-mediated fusion with the host cell. It has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). It significantly reduced viral load in a phase 2 RSV human challenge study in healthy adults and is currently being evaluated in a global phase 2 clinical study in children.

Further clinical studies in adults and children are being planned and will be initiated following feedback from regulatory agencies.

About the Pfizer and LianBio Strategic Collaboration
In 2020, LianBio and Pfizer entered into a collaboration aimed at developing and commercializing transformative pharmaceutical products in Greater China leveraging both LianBio's and Pfizer's clinical development, regulatory and commercial expertise. Under the terms of the collaboration, Pfizer will contribute up to $70M of non-dilutive capital toward in-licensing, development and commercialization. At LianBio's discretion, products are presented to Pfizer, and Pfizer can opt-in to development and commercial rights. The first program under development as part of the Pfizer and LianBio strategic collaboration is sisunatovir, an investigational therapeutic for the treatment of RSV in pediatric and adult patients.

Pfizer Inc: Breakthroughs that change patients' lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com.cn.

Pfizer Disclosure Notice

The information contained in this release is as of December 19, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a strategic collaboration between Pfizer and LianBio to expand patient access to novel therapeutics in Mainland China, Hong Kong, Macau and Singapore, including Pfizer's right to develop and commercialize sisunatovir, a respiratory syncytial virus (RSV) therapeutic candidate. Pfizer's research and development of RSV vaccines and therapeutics, despite their potential benefits, may involve substantial risks and uncertainties that could cause actual

results to differ materially from those expressed or implied by any statements or information contained in this release. Such risks and uncertainties may include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including the data discussed in this release), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when applications may be filed in any jurisdiction for any potential indications for any candidates resulting from this collaboration or any drug applications for any potential indications for sisunatovir or any other Pfizer RSV vaccines or therapeutic candidates which may be filed in particular jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications for any candidates resulting from this collaboration or applications or submissions for sisunatovir or any other Pfizer RSV vaccines or therapeutic candidates that may be pending or filed, which will depend on a myriad of factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any candidates resulting from this collaboration will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any candidates resulting from this collaboration or applications or submission for sisunatovir or any other Pfizer RSV vaccines or therapeutic candidates, including development of products or therapies by other companies; whether our collaboration with LianBio will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and any other competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About LianBio

LianBio is a cross-border biotechnology company on a mission to bring transformative medicines to 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 additional information, please visit the company's website at www.lianbio.com.

LianBio's 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 " believe," "expect," "potential," "may" "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 press release include, but are not limited to, statements concerning the promise of sisunatovir to address significant treatment gaps for patient populations vulnerable to severe complications of RSV, the potential for the companies' collaboration to provide more patients with access to a much-needed therapy, susunatovir's ability to change the standard of care for patients with RSV disease and the Company's timing of planned 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 Annual Report on Form 10-K for the year ended December 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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