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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2022

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-40947

LianBio

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**98-1594670**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. 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

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, par value $0.000017100448 per share	**LIAN**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of November 7, 2022, 108,353,831 ordinary shares of the registrant, par value $0.000017100448 per share, were outstanding, of which 41,031,784 ordinary shares were held in the form of American Depositary Shares. This total number of ordinary shares and total number of ordinary shares held in the form of American Depositary Shares excludes 2,175,095 ordinary shares that are held by the depositary on reserve to satisfy obligations of the registrant under the registrant's equity plans.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, about us and our industry that involve substantial risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, prospects, plans, objectives of management and expected growth, are forward-looking statements. These statements are based on our current beliefs, expectations and assumptions regarding our intentions, beliefs or current expectations concerning, among other things, the future of our business, future plans and strategies, our operational results and other future conditions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Forward-looking statements can be identified by words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “seek,” “target,” “will,” “would,” “could,” “should,” “continue,” “contemplate” and other similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our ability to successfully develop, gain regulatory approval for and launch commercial products in Greater China and other Asian markets;
- our ability to deliver innovative therapeutic solutions to patients and become a leading biopharmaceutical company in Greater China, including Mainland China, Hong Kong, Taiwan and Macau, and other Asian markets;
- our plans and ability to leverage data generated in our partners’ global registrational trials and clinical development programs to obtain regulatory approval for and bring our current product candidates to market in our licensed territories, and our plans to maximize patient reach for each of our product candidates;
- our partners’ announced plans and expectations with respect to the success, cost and timing of their product development activities, preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the timing of expected review from regulatory authorities and the period during which the results of the trials are expected to become available;
- our ability to expand our pipeline through the continued strategic in-licensing of innovative and complementary product candidates with the potential to become the new standard of care in Greater China and other Asian markets;
- our ability to successfully establish an international infrastructure, including by building a focused salesforce in China and leveraging the commercial infrastructure we create to benefit our other assets;
- our ability to establish and maintain relationships and collaborations with investors and our current and any future licensing partners that will contribute to our success in sourcing value and creating partnerships to enable us to build out a broad and clinically validated pipeline;
- our ability to design, initiate and complete any clinical trials to advance our current product candidates, including mavacamten, TP-03, NBTXR3, infigratinib, BBP-398, LYR-210, omilancor, NX-13 and sisunatovir, as well as any future product candidates, towards regulatory approval in China and our other licensed territories;
- our ability to conduct, and the timing of and costs related to, our product development activities, including any preclinical studies and related clinical trials in Greater China and other Asian markets of our current and any future product candidates, and our ability to obtain, and the timing of and costs related to, potential regulatory approval of such product candidates in Greater China and other Asian markets;
- our plans to pursue the development of certain product candidates for additional treatment indications;
- our ability to successfully utilize the data we may generate from any clinical trials we conduct in Greater China or other territories, including in conjunction with data from clinical trials conducted by our partners, to seek regulatory approval in Greater China and other Asian markets;
- our plans and ability to join our current and future partners’ clinical and registrational trials and our plans and ability to initiate and complete our standalone clinical and registrational trials;

- our ability to design and implement the development strategies for our product candidates in each of our licensed territories and, where applicable, our ability to design and implement global development strategies for our product candidates in new indications in connection with our local development strategies;
- the potential for certain of our current and future product candidates to have more benign safety profiles or result in differentiated safety profiles than currently available therapeutic options;
- the size, composition and growth potential of the patient populations and markets we intend to target with our product candidates and our ability to develop and commercialize product candidates to address those patient populations and markets;
- our ability to successfully procure from our partners or other third parties, as applicable, sufficient supply of our product candidates for any preclinical studies, clinical trials or commercial use, if approved;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates and our general and administrative expenses;
- the rate and degree of market acceptance of our product candidates;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations and of any legal and regulatory developments in our licensed territories or internationally;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to license intellectual property relating to our product candidates and to comply with our existing license and collaboration agreements;
- our reliance on third parties to conduct product development, manufacturing and other services, and any agreements we have or into which we may enter with such parties in connection with the commercialization of our product candidates and any other approved product;
- our expectations regarding the time during which we will be an emerging growth company or smaller reporting company;
- the direct and indirect impact of the COVID-19 pandemic on our business, operations (including clinical trials) and the markets and communities in which we and our partners, collaborators and vendors operate;
- our estimates of our expenses, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

Although we base these forward-looking statements on assumptions that we believe are reasonable when made, we caution investors that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, those results or developments may not be indicative of results or developments in subsequent periods.

Given these risks and uncertainties, investors are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statement that we make in this Quarterly Report on Form 10-Q speaks only as of the date of such statement, and we undertake no obligation to update any forward-looking statements or to publicly announce the results of any revisions to any of those statements to reflect future events or developments. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless specifically expressed as such, and should only be viewed as historical data. Investors should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Unless the context requires otherwise, references in this report to the “Company,” “LianBio,” “we,” “us” and “our” refer to LianBio and its consolidated subsidiaries.

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 78,862	$ 228,182
Marketable securities	232,866	155,067
Prepaid expenses and other current assets	5,117	10,354
Other receivable	7,393	6,044
Total current assets	324,238	399,647
Restricted cash, non-current	20,070	20,000
Property and equipment, net	3,135	1,882
Operating lease right-of-use assets	4,362	4,763
Other non-current assets	37	51
Total assets	$ 351,842	$ 426,343
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,019	$ 3,231
Accrued expenses	17,871	9,976
Current portion of operating lease liabilities	1,750	1,125
Other current liabilities	387	760
Total current liabilities	22,027	15,092
Operating lease liabilities	3,017	3,709
Other liabilities	200	206
Nonrefundable research deposit	20,000	20,000
Total liabilities	$ 45,244	$ 39,007
Commitments and contingencies (Note 8)		
Shareholders' equity (deficit):		
Ordinary shares, $0.000017100448 par value. 2,923,900,005 shares authorized as of September 30, 2022; 108,353,831 shares issued and outstanding as of September 30, 2022; 2,923,900,005 shares authorized as of December 31, 2021; 107,275,458 shares issued and outstanding as of December 31, 2021	2	2
Additional paid-in capital	728,915	713,269
Accumulated other comprehensive (loss) income	(3,844)	526
Accumulated deficit	(452,249)	(360,235)
Total LianBio shareholders' equity	272,824	353,562
Non-controlling interest	33,774	33,774
Total shareholders' equity	306,598	387,336
Total liabilities and shareholders' equity	$ 351,842	$ 426,343

See accompanying notes to the consolidated financial statements

LianBio
Consolidated 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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 8,258	$ 4,655	$ 49,178	$ 151,038
General and administrative	16,291	8,889	46,930	22,496
Total operating expenses	24,549	13,544	96,108	173,534
Loss from operations	(24,549)	(13,544)	(96,108)	(173,534)
Other income (expense):				
Interest income, net	1,405	32	2,238	171
Other income (expense), net	1,253	3	1,873	(189)
Net loss before income taxes	(21,891)	(13,509)	(91,997)	(173,552)
Income taxes (benefit)	6	(397)	17	1,553
Net loss	(21,897)	(13,112)	(92,014)	(175,105)
Other comprehensive (loss) income:				
Foreign currency translation (loss) income, net of tax	(2,282)	(26)	(3,096)	104
Unrealized loss on marketable securities, net of tax	(160)	—	(1,274)	—
Comprehensive loss	$ (24,339)	$ (13,138)	$ (96,384)	$ (175,001)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.20)	$ (0.63)	$ (0.85)	$ (8.52)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	108,353,831	20,690,908	107,854,547	20,549,310

See accompanying notes to the consolidated financial statements

LianBio
Consolidated Statements of Redeemable Convertible Preferred Shares and Shareholders' Equity (Deficit)
(In thousands, except share amounts)
(Unaudited)

	Redeemable Convertible Preferred Shares		Ordinary Shares		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total LianBio Shareholders' Equity	Non-Controlling Interest	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
Balance, December 31, 2021	—	$ —	107,275,458	$ 2	$ 713,269	$ 526	$ (360,235)	$ 353,562	$ 33,774	$ 387,336
Share-based compensation expense	—	—	—	—	4,669	—	—	4,669	—	4,669
Receivable from related party	—	—	—	—	1,710	—	—	1,710	—	1,710
Net Loss	—	—	—	—	—	—	(27,726)	(27,726)	—	(27,726)
Comprehensive Loss	—	—	—	—	—	(1,216)	—	(1,216)	—	(1,216)
Balance, March 31, 2022	—	$ —	107,275,458	$ 2	$ 719,648	$ (690)	$ (387,961)	$ 330,999	$ 33,774	$ 364,773
Share-based compensation expense	—	—	—	—	4,528	—	—	4,528	—	4,528
Exercise of options	—	—	1,000,000	—	—	—	—	—	—	—
Exercise of warrants	—	—	78,373	—	—	—	—	—	—	—
Net Loss	—	—	—	—	—	—	(42,391)	(42,391)	—	(42,391)
Comprehensive Loss	—	—	—	—	—	(712)	—	(712)	—	(712)
Balance, June 30, 2022	—	$ —	108,353,831	$ 2	$ 724,176	$ (1,402)	$ (430,352)	$ 292,424	$ 33,774	$ 326,198
Share-based compensation expense	—	—	—	—	4,739	—	—	4,739	—	4,739
Net Loss	—	—	—	—	—	—	(21,897)	(21,897)	—	(21,897)
Comprehensive Loss	—	—	—	—	—	(2,442)	—	(2,442)	—	(2,442)
Balance, September 30, 2022	—	$ —	108,353,831	$ 2	$ 728,915	$ (3,844)	$ (452,249)	$ 272,824	$ 33,774	$ 306,598

LianBio
Consolidated Statements of Redeemable Convertible Preferred Shares and Shareholders' Equity (Deficit)
(In thousands, except share amounts)
(Unaudited)

	Redeemable Convertible Preferred Shares		Ordinary Shares		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total LianBio Shareholders' Equity (Deficit)	Non-Controlling Interest	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
Balance, December 31, 2020	10,971,231	$ 349,789	20,477,338	$ —	$ 31,132	$ (40)	$ (163,935)	$ (132,843)	$ 34,773	$ (98,070)
Share-based compensation expense	—	—	—	—	1,674	—	—	1,674	—	1,674
Issuance of Series A Preferred Shares at $56.66, net of issuance costs	52,947	2,940	—	—	—	—	—	—	—	—
Warrants issued in license agreement	—	—	—	—	—	—	—	—	9,415	9,415
Net Loss	—	—	—	—	—	—	(61,565)	(61,565)	—	(61,565)
Comprehensive Income	—	—	—	—	—	8	—	8	—	8
Balance, March 31, 2021	11,024,178	$ 352,729	20,477,338	$ —	$ 32,806	$ (32)	$ (225,500)	$ (192,726)	$ 44,188	$ (148,538)
Share-based compensation expense	—	—	—	—	1,443	—	—	1,443	—	1,443
Net Loss	—	—	—	—	—	—	(100,428)	(100,428)	—	(100,428)
Comprehensive Income	—	—	—	—	—	122	—	122	—	122
Balance, June 30, 2021	11,024,178	$ 352,729	20,477,338	$ —	$ 34,249	$ 90	$ (325,928)	$ (291,589)	$ 44,188	$ (247,401)
Share-based compensation expense	—	—	—	—	2,168	—	—	2,168	—	2,168
Exercise of options	—	—	1,309,907	—	5,309	—	—	5,309	—	5,309
Net Loss	—	—	—	—	—	—	(13,112)	(13,112)	—	(13,112)
Comprehensive Loss	—	—	—	—	—	(26)	—	(26)	—	(26)
Balance, September 30, 2021	11,024,178	$ 352,729	21,787,245	$ —	$ 41,726	$ 64	$ (339,040)	$ (297,250)	$ 44,188	$ (253,062)

LianBio
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net loss	$ (92,014)	$ (175,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash share consideration, issued in acquisition of IPR&D	—	9,415
Non-cash operating lease expense (benefit)	354	(76)
Depreciation expense	689	278
Share based compensation expense	13,936	5,285
Amortization of discounts on investments, net	(481)	—
Unrealized foreign currency transaction gain, net	(1,375)	(56)
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	4,794	(3,801)
(Increase) decrease in other receivable	(1,244)	14,216
Decrease in other non-current assets	11	2
Decrease in accounts payable	(1,091)	(2,690)
Increase in accrued expenses	8,197	11,568
(Decrease) increase in other current liabilities	(248)	1,434
Increase in withholding tax payable	—	5,957
Net cash used in operating activities	(68,472)	(133,573)
Cash flows from investing activities:		
Purchase of property and equipment	(1,610)	(159)
Purchase of marketable securities	(260,367)	—
Sales and redemption of marketable securities	181,780	—
Net cash used for investing activities	(80,197)	(159)
Cash flows from financing activities:		
Proceeds from exercise of share options	1,710	5,309
Proceeds from issuance of redeemable convertible preferred shares	—	3,000
Issuance costs related to redeemable convertible preferred shares	—	(60)
Net cash provided by financing activities	1,710	8,249
Effect of exchange rate changes on cash and cash equivalents	(2,291)	148
Net decrease in cash, cash equivalents and restricted cash	$ (149,250)	$ (125,335)
Cash and cash equivalents, and restricted cash—beginning of period	248,182	254,350
Cash and cash equivalents, and restricted cash—ending of period	$ 98,932	$ 129,015
Cash and cash equivalents—end of period	$ 78,862	$ 109,015
Restricted cash—end of period	$ 20,070	$ 20,000
Cash and cash equivalents, and restricted cash—ending of period	$ 98,932	$ 129,015
Supplemental disclosure of cash information		
Cash paid for income taxes	$ 523	$ —
Supplemental disclosure of non-cash operating activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 1,233	$ 247
Issuance costs in accounts payable and other accrued liabilities	$ —	$ 3,310
Purchase of property and equipment in accounts payable	$ 551	$ —

See accompanying notes to the consolidated financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Tabular Dollars in Thousands, Except Share and per Share Data)
(Unaudited)

1. Nature of Business

LianBio ("LianBio" or the "Company") is a global, science-driven biopharmaceutical company dedicated to developing and commercializing innovative medicines for patients with unmet medical needs, with an initial focus on in-licensing assets for Greater China and other Asian markets.

The Company was incorporated in the Cayman Islands in July 2019 and maintains its Chinese headquarters in Shanghai, China. The Company conducts its corporate activities at its United States headquarters located in Princeton, New Jersey.

On November 3, 2021, the Company completed its initial public offering ("IPO") through an underwritten sale of 20,312,500 American Depositary Shares ("ADSs") representing 20,312,500 ordinary shares at a price of $16.00 per share. Following the close of the IPO, on December 1, 2021, the underwriters partially exercised their option to purchase additional shares and purchased an additional 593,616 ADSs at the IPO price of $16.00 per ADS. The Company received gross proceeds of $334.5 million in connection with the IPO and subsequent exercise of the underwriters' option and aggregate net proceeds of $304.8 million after deducting underwriting discounts, commissions and other offering expenses.

Concurrent with the IPO, all of the Company's convertible preferred shares then-outstanding were automatically converted into an aggregate of 64,467,176 ordinary shares and were reclassified into permanent equity. Following the IPO, there were no preferred shares outstanding.

2. Significant Accounting Policies

(A) Basis of presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, which include the People's Republic of China ("PRC") registered entities directly owned by the Company. All intercompany accounts and transactions have been eliminated in consolidation.

The interim balance sheet as of September 30, 2022, and the interim consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred shares and shareholders' equity (deficit) for the three and nine months ended September 30, 2022 and 2021, and the cash flows for the nine months ended September 30, 2022 and 2021 are unaudited. These unaudited interim financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, which consist of only normal recurring adjustments, necessary for the fair statement of the Company's financial information. The financial data and other information disclosed in these notes related to the three and nine month periods are also unaudited. The interim results for the three and nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods or any future year or period.

(B) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported financial position at the date of the financial statements and the reported results of operations during the reporting period. Such estimates and assumptions affect the reported amounts of assets, liabilities, and expenses, and disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. The only material estimates in the accompanying financial statements are the fair value of warrants, share-based compensation, and share options. Actual results could differ from those used in evaluating these accounting estimates.

(i) Concentration of Credit Risk and Other Risks and Uncertainties

In March 2020, the World Health Organization declared the global novel coronavirus disease 2019 ("COVID-19") outbreak a pandemic. The Company's operations have not been significantly impacted by the COVID-19 pandemic. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its financial condition and operations, including planned clinical trials. The impact of the COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy continue to be impacted for an extended period, the Company's results may be materially adversely affected.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents in deposits at financial institutions that exceed federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to material credit risk due to the financial position of the banking institutions. The Company has no off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

The Company's results of operations involve numerous risks and uncertainties. Factors that could affect the Company's operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials, uncertainty of regulatory approval of the Company's potential product candidates, uncertainty of market acceptance of its product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

Each of the Company's product candidates require approvals from the National Medical Products Administration ("NMPA") in China and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval for any product candidate, such events could have a materially adverse impact on the Company's business.

(ii) Liquidity

The Company has incurred operating losses since inception and had an accumulated deficit of $452.2 million as of September 30, 2022 and $360.2 million as of December 31, 2021. The Company's cash and cash equivalents and marketable securities were $311.7 million and $383.2 million as of September 30, 2022 and December 31, 2021, respectively. The Company has financed its operations to date primarily through equity capital raises.

The Company believes that existing capital resources will be sufficient to meet projected operating requirements for at least 12 months from the date of issuance of the accompanying consolidated financial statements, though it expects to continue to incur operating losses and negative operating cash flows. The Company will be required to raise additional capital to fund future operations, however, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to preserve cash resources. These factors may adversely impact the Company's ability to achieve its business objectives and would likely have an adverse effect on its future business prospects, or even its ability to remain a going concern.

(C) Significant Accounting Policies Update

The Company's significant accounting policies are disclosed in Note 2, *Significant Accounting Policies* in the Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to the Company's significant accounting policies during the three and nine months ended September 30, 2022.

(D) Recently Issued Accounting Pronouncements Not Yet Adopted

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. As an emerging growth company, the Company has elected to "opt out" of such extended transition period for the implementation of new or revised accounting standards and, as a result, the Company will comply with new or revised accounting standards on the same timeline as other public companies. The Company has evaluated recent accounting pronouncements and believes that there are none that will have a material impact on its financial position or results of operations upon adoption.

3. Material Agreements

License Agreement with QED Therapeutics, Inc.

In October 2019, the Company entered into a license agreement (as subsequently amended, the "QED License Agreement") with QED Therapeutics, Inc. ("QED"), under which the Company obtained an exclusive license under certain patents and know-how (including patents and know-how that QED licensed from QED's upstream licensor) to develop, manufacture, use, sell, import, and commercialize QED's ATP-competitive, FGFR1-3 tyrosine kinase inhibitor, infigratinib, in pharmaceutical products in the licensed territory of Mainland China, Macau, Hong Kong, Taiwan, Thailand, Singapore and South Korea, in the licensed field of human prophylactic and therapeutic uses in cancer indications. In September 2020, the Company entered into an amendment with QED to reduce the licensed territories to include Mainland China, Macau and Hong Kong. In December 2021, the Company entered into a second amendment with QED to modify the Company's development obligations with respect to certain clinical trials, and change the development milestone payments the Company owes to QED and the royalty rates for the tiered royalties on net sales of licensed products the Company will pay to QED. Under the QED License Agreement, QED received a nonrefundable upfront payment of $10.0 million and was granted warrants to purchase 100,000 ordinary shares in Lian Oncology, a subsidiary of LianBio, valued at $1.0 million. Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model. The warrants were issued in three tranches with the aggregate number of shares across all tranches equaling 10% of the fully diluted equity of Lian Oncology as of the issue date. Vesting of the warrant shares are linked to regulatory milestones and the warrants expire 10 years from the issue date. The amended and restated option agreement also provides QED with the option to choose to either convert the warrant ("Subsidiary Warrant") into ordinary shares of the Company ("Parent Company Shares") or a warrant to purchase a certain number of Parent Company Shares ("Parent Company Warrant") immediately prior to an IPO of the Company. In the event QED chose to convert the Subsidiary Warrant into Parent Company Shares, the number of Parent Company Shares QED is entitled to receive would be calculated as the aggregate fair market value of the ordinary shares of Lian Oncology that are under the Subsidiary Warrant, divided by the per share fair market value of the Parent Company Shares, on a fully diluted and as-converted basis and as of the date the Company sent QED the notice of the IPO. In the event QED chose to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant QED was entitled to receive would have been calculated as the aggregate intrinsic value of the Subsidiary Warrant (the number of the ordinary shares of Lian Oncology under the Subsidiary Warrant multiplied by the difference between the strike price of the Subsidiary Warrant and the per share fair market value of Lian Oncology), divided by the per share intrinsic value of the Parent Company Warrant (the difference between the strike price of the Parent Company Warrant and the per share fair market value of Parent Company Shares), on a fully diluted and as-converted basis on the date of the warrant conversion. This conversion feature was not required to be bifurcated as it is clearly and closely related to the equity host instrument, pursuant to ASC 815. On October 18, 2021, based on the conversion feature, LianBio issued to QED a warrant to purchase 347,569 of its ordinary shares at an exercise price of $0.000017100448 per share and, concurrently with such issuance, the Subsidiary Warrant was deemed to be performed and settled in full and was irrevocably terminated. The QED License Agreement also required the Company to refund QED for costs incurred on the study through the execution date which was determined to be $2.8 million. Additionally, QED is entitled to receive from the Company development milestone payments of up to $7.0 million upon achievement of specified development milestones, and sales milestone payments of up to $87.5 million based on cumulative net sales of infigratinib, in addition to tiered royalties on net sales of licensed products at the greater of (a) percentage rates in the mid- to high-teens on the net sales of the licensed products, or (b) the applicable rate payable under QED's agreement with its upstream licensor (capped in the mid-teens).

License Agreement with MyoKardia

In August 2020, the Company entered into an exclusive license agreement (the "MyoKardia License Agreement") with MyoKardia Inc. ("MyoKardia," now a wholly-owned subsidiary of Bristol-Myers Squibb ("BMS")), under which the Company obtained an exclusive license under certain patents and know-how of MyoKardia to develop, manufacture, use, sell, import and commercialize MyoKardia's proprietary compound, mavacamten, in the licensed territory of Mainland China, Hong Kong, Macau, Taiwan, Thailand and Singapore, and in the licensed field of any indication in humans, which includes any prophylactic or therapeutic use in humans. Under the MyoKardia License Agreement, MyoKardia received a nonrefundable upfront payment of $40.0 million and was granted a warrant to purchase 170,000 ordinary shares in Lian Cardiovascular, a subsidiary of LianBio, valued at $33.8 million. Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model and the underlying assumptions are discussed in further detail in Note 10 in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. The warrants, representing 17% of the fully diluted equity of Lian Cardiovascular, are exercisable by MyoKardia at any time after issuance. The amended and restated option agreement also provides MyoKardia with the option to choose to either convert the warrant ("Subsidiary Warrant") into ordinary shares of the Company ("Parent Company Shares") or a warrant to purchase a certain number of Parent Company Shares ("Parent Company Warrant") immediately prior to an IPO of the Company. MyoKardia was entitled to choose to convert the Subsidiary Warrant into Parent Company Shares, and the number of Parent Company Shares MyoKardia was entitled to receive would have been calculated as the aggregate fair market value of the ordinary shares of Lian Cardiovascular that are under the Subsidiary Warrant, divided by the per share fair market value of the Parent Company Shares, on a fully diluted and as-converted basis on the date the Company sent MyoKardia the notice of the IPO. Alternatively, MyoKardia was entitled to choose to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant MyoKardia was entitled to receive would be calculated as the aggregate intrinsic value of the Subsidiary Warrant (the number of the ordinary shares of Lian Cardiovascular under the Subsidiary Warrant multiplied by the difference between the strike price of the Subsidiary Warrant and the per share fair market value of Lian Cardiovascular), divided by the per share intrinsic value of the Parent Company Warrant (the difference between the strike price of the Parent Company Warrant and the per share fair market value of Parent Company Shares), on a fully diluted and as-converted basis on the date of the warrant conversion. This conversion feature was not required to be bifurcated as it was clearly and closely related to the equity host instrument, pursuant to ASC 815. As of October 12, 2021, MyoKardia elected not to exercise this option and, therefore, continues to hold its warrant to purchase 170,000 ordinary shares in Lian Cardiovascular. MyoKardia's option to convert the warrant irrevocably terminated upon the completion of the Company's IPO. Additionally, MyoKardia was entitled to receive a nonrefundable financing milestone payment of $35.0 million upon a specified financing event, which occurred on October 29, 2020. The financing milestone was recorded at present value upon execution of the MyoKardia License Agreement, with total imputed interest of $2.3 million accreted under the effective interest method through the date the liability was settled. The financing milestone was paid to MyoKardia in December 2020 as a result of the Series A Preferred financing. Additionally, MyoKardia is entitled to receive from the Company development milestone payments of up to $60.0 million upon achievement of specified development milestones, and sales milestone payments of up to $87.5 million based on cumulative net sales of mavacamten, plus tiered royalties on net sales ranging from the low to upper-teens. As of September 30, 2022, the Company has paid $5.0 million to MyoKardia upon the completion of the first development milestone under the MyoKardia License Agreement.

License Agreement with Navire

In August 2020, pursuant to the BridgeBio exclusivity agreement, the Company entered into an exclusive license agreement with Navire Pharma, Inc. ("Navire"), a BridgeBio affiliate. Pursuant to the license agreement, Navire granted to the Company an exclusive, sublicensable license under certain patents and know-how of Navire to develop, manufacture, use, sell, import and commercialize Navire's proprietary SHP2 inhibitor, BBP-398 (formerly known as IACS-15509) in the licensed territory of Mainland China, Hong Kong, Macau, Taiwan, Thailand, Singapore, and South Korea. Under the license agreement, Navire received a nonrefundable upfront payment of $8.0 million. Additionally, Navire is entitled to receive from the Company development milestone payments of up to $24.5 million upon achievement of specified development milestones, and sales milestone payments of up to $357.6 million upon achievement of specified commercialization milestones, plus tiered royalties on net sales ranging from approximately 5-15% on the net sales of the licensed products. The Company paid the first development milestone of $8.5 million for IND acceptance in the PRC during the third quarter of 2021.

Pfizer Strategic Collaboration

In November 2020, the Company entered into a strategic collaboration agreement (the "Pfizer Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which Pfizer will contribute up to $70.0 million of restricted, non-dilutive capital (the "Funds"), including a $20.0 million upfront payment, toward the Company's in-licensing and co-development activities in Greater China. The Company has accounted for the Pfizer Agreement as a contract to perform research and development services for others under ASC 730-20 and the consideration received for performing these services will be recognized as contra-R&D in the consolidated statement of operations as the services are performed. Upon receipt of the $20.0 million upfront payment in the first quarter of 2021, the upfront payment was recorded as restricted cash within consolidated balance sheet and will remain restricted until such time as the upfront payment is utilized for specified in-licensing and co-development activities or until the Pfizer Agreement terminates. Under the Pfizer Agreement, Pfizer and LianBio will form a joint collaboration committee to discuss potential third party in-license opportunities and development and commercialization of the Company's products in Greater China. In the event the Company seeks to engage a third-party commercialization partner with respect to the commercialization of the Company's future products in Greater China, Pfizer will have a right to opt into such product. Upon opting in, a portion of the Funds will be used to pay for development and commercialization costs of such product and Pfizer will thereafter have a right of first negotiation and right of last refusal to obtain the commercialization rights of such product in Greater China, in each instance for additional, separate financial consideration. During the collaboration, Pfizer may provide in-kind support to us for marketing, development and regulatory activities.

License Agreement with ReViral

In March 2021, the Company entered into an exclusive license agreement (the "ReViral License Agreement") with ReViral Ltd. ("ReViral," now a wholly-owned subsidiary of Pfizer). Pursuant to the license agreement, ReViral granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize novel antiviral therapeutics that target respiratory syncytial virus in Mainland China, Macau, Hong Kong, and Singapore. Under the license agreement, ReViral received a nonrefundable upfront payment of $14.0 million. Additionally, ReViral is entitled to receive payments from the Company totaling an aggregate of up to $105.0 million upon the achievement of specified development and commercial milestones, up to $45.0 million and $60.0 million, respectively, plus tiered royalties on net sales ranging from ten to the low-teens.

License Agreement with Tarsus

In March 2021, the Company entered into an exclusive license agreement (the "Tarsus License Agreement") with Tarsus Pharmaceuticals, Inc. ("Tarsus"). Pursuant to the license agreement, Tarsus granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize TP-03 for the treatment of patients with Demodex blepharitis and Meibomian Gland Disease in Mainland China, Macau, Hong Kong and Taiwan. Under the license agreement, Tarsus received a nonrefundable upfront payment of $15.0 million and was granted three warrants to purchase 125,000 ordinary shares in Lian Ophthalmology, a subsidiary of LianBio, valued at $9.4 million (the "Tarsus Warrants"). Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model and the underlying assumptions are discussed in further detail in Note 10 in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. The warrants were issued in three tranches with the aggregate number of shares across all tranches equaling 12.5% of the fully diluted equity of Lian Ophthalmology as of the issue date. Vesting of the warrant shares are linked to regulatory milestones and the warrants expire 10 years from the issue date. Pursuant to a related option agreement (the "Tarsus Option Agreement"), Tarsus also had the option to convert the warrants into ordinary shares of the Company or warrants to purchase a certain number of the Company's ordinary shares based on appreciation of the value in the Lian Ophthalmology since the inception of the Tarsus License Agreement. This conversion feature was not required to be bifurcated as it was clearly and closely related to the equity host instrument, pursuant to ASC 815. On October 18, 2021, Tarsus exercised its options to convert the Tarsus Warrants under the Tarsus Option Agreement and the Company subsequently issued to Tarsus 78,373 of its ordinary shares and two warrants to purchase an aggregate of 156,746 of its ordinary shares at an exercise price of $0.000017100448 per share. Following the issuances, the Tarsus Warrants were irrevocably terminated. On June 6, 2022, Tarsus exercised one warrant and the Company subsequently issued 78,373 of its ordinary shares at an exercise price of $0.000017100448 per share. Additionally, Tarsus is entitled to receive a nonrefundable second milestone payment of $10.0 million due and payable within forty-five days following the effective date. Furthermore, Tarsus is entitled to receive payments from the Company totaling an aggregate of up to $175.0 million upon the achievement of specified development and commercial milestones, up to $75.0 million and $100.0 million, respectively, plus tiered royalties at percentage rates ranging from the low- to high-teens on net sales. In the second quarter of 2022, the Company was notified that Tarsus had achieved a certain development milestone and subsequently paid $15 million in June 2022. As of September 30, 2022, the Company has paid an aggregate of $45.0 million to Tarsus as a result of the achievement of various development milestones.

License Agreement with Landos

In May 2021, the Company entered into an exclusive license agreement (the "Landos License Agreement") with Landos BioPharma, Inc. ("Landos"). Pursuant to the license agreement, Landos granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize novel, gut-restricted small molecule omilancor (formerly known as BT-11) and NX-13 for the treatment of inflammatory bowel disease, that targets the NLRX1 pathway in Mainland China, Hong Kong, Macau, Taiwan, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand and Vietnam. Under the license agreement, Landos received a nonrefundable upfront payment of $18.0 million. Additionally, Landos is entitled to receive payments from the Company totaling an aggregate of up to $200.0 million upon the achievement of specified development and commercial milestones, up to $95.0 million and $105.0 million, respectively, plus tiered royalties at percentage rates ranging from the low- to the mid-teens on net sales.

License Agreement with Nanobiotix

In May 2021, the Company entered into an exclusive license agreement (the "Nanobiotix License Agreement") with Nanobiotix S.A. ("Nanobiotix"). Pursuant to the license agreement, Nanobiotix granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop and commercialize NBTXR3, a potential first-in-class radioenhancer in Mainland China, Hong Kong, Taiwan, Macau, South Korea, Singapore and Thailand. Under the license agreement, Nanobiotix received a nonrefundable upfront payment of $20.0 million. Additionally, Nanobiotix is entitled to receive payments from the Company totaling an aggregate of up to $220.0 million upon the achievement of specified development and commercial milestones, up to $65.0 million and $155.0 million, respectively, plus tiered royalties of 10-13% of net sales.

License Agreement with Lyra

In May 2021, the Company entered into an exclusive license agreement (the "Lyra License Agreement") with Lyra Therapeutics, Inc. ("Lyra"). Pursuant to the license agreement, Lyra granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop and commercialize LYR-210, an anti-inflammatory, intra-nasal drug matrix in late-stage development that is designed to treat chronic rhinosinusitis in Mainland China, Hong Kong, Taiwan, Macau, South Korea, Singapore and Thailand. Under the license agreement, Lyra received a nonrefundable upfront payment of $12.0 million. Additionally, Lyra is entitled to receive payments from the Company totaling an aggregate of up to $135.0 million upon the achievement of specified development and commercial milestones, up to $40.0 million and $95.0 million, respectively, plus tiered royalties from the low- to high-teens on net sales. As of September 30, 2022, the Company has paid for the first development milestone of $5.0 million.

4. Marketable Securities and Fair Value Measurements

The following is a summary of marketable securities accounted for as available-for-sale securities at September 30, 2022 and December 31, 2021:

As of September 30, 2022 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 155,652	$ —	$ (574)	$ 155,078
Corporate debt securities	14,202	—	(136)	14,066
Government obligations & agency securities	64,232	1	(511)	63,722
Total	$ 234,086	$ 1	$ (1,221)	$ 232,866

As of December 31, 2021 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 145,894	$ 55	$ —	$ 145,949
Corporate debt securities	4,138	—	—	4,138
Government obligations	4,986	—	(6)	4,980
Total	$ 155,018	$ 55	$ (6)	$ 155,067

The unrealized losses and fair values of available-for-sale securities that have been in an unrealized loss position for a period of less than and greater than 12 months as of September 30, 2022 are as follows:

As of September 30, 2022 (in thousands)	Securities in an unrealized loss position less than 12 months		Securities in an unrealized loss position greater than 12 months		Total	
	Unrealized losses	Fair Value	Unrealized losses	Fair Value	Unrealized losses	Fair Value
Commercial paper	$ (574)	$ 147,581	$ —	$ —	$ (574)	$ 147,581
Corporate debt securities	(136)	14,065	—	—	(136)	14,065
Government obligations & agency securities	(465)	46,795	(46)	14,952	(511)	61,747
Total	$ (1,175)	$ 208,441	$ (46)	$ 14,952	$ (1,221)	$ 223,393

The unrealized losses and fair values of available-for-sale securities that have been in an unrealized loss position for a period of less than and greater than 12 months as of December 31, 2021 are as follows:

As of December 31, 2021 (in thousands)	Securities in an unrealized loss position less than 12 months		Securities in an unrealized loss position greater than 12 months		Total	
	Unrealized losses	Fair Value	Unrealized losses	Fair Value	Unrealized losses	Fair Value
Commercial paper	$ —	$ —	$ —	$ —	$ —	$ —
Corporate debt securities	—	—	—	—	—	—
Government obligations	(6)	4,980	—	—	(6)	4,980
Total	$ (6)	$ 4,980	$ —	$ —	$ (6)	$ 4,980

Marketable securities on the balance sheet at September 30, 2022 and December 31, 2021 are as follows:

	September 30, 2022	
	Less than 12 Months	More Than 12 Months
Commercial paper	$ 155,078	$ —
Corporate debt securities	14,066	—
Government obligations & agency securities	46,795	16,927
Total Marketable securities	$ 215,939	$ 16,927

	December 31, 2021	
	Less than 12 Months	More Than 12 Months
Commercial paper	$ 145,949	$ —
Corporate debt securities	4,138	—
Government obligations	—	4,980
Total Marketable securities	$ 150,087	$ 4,980

The Company classifies all of its securities as current as they are all available for sale and are available for current operations.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

As of September 30, 2022 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 53,472	$ —	$ —	$ 53,472
Commercial paper	—	4,988	—	4,988
Marketable securities:				
Commercial paper	—	155,078	—	155,078
Corporate debt securities	—	14,065	—	14,065
Government obligations & agency securities	—	63,723	—	63,723
Total	$ 53,472	$ 237,854	$ —	$ 291,326

As of December 31, 2021 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 67,289	$ —	$ —	$ 67,289
Commercial paper	—	80,541	—	80,541
Corporate debt securities	—	8,165	—	8,165
Marketable securities:				
Commercial paper	—	145,949	—	145,949
Corporate debt securities	—	4,138	—	4,138
Government obligations	—	4,980	—	4,980
Total	$ 67,289	$ 243,773	$ —	$ 311,062

5. Property and Equipment, Net

Property and equipment consisted of the following:

	September 30, 2022	December 31, 2021
Leasehold improvements	$ 2,717	$ 807
Furniture and fixtures	113	65
Computer equipment and software	794	471
Construction in progress	723	1,145
	4,347	2,488
Accumulated depreciation	(1,212)	(606)
Total property and equipment, net	$ 3,135	$ 1,882

Total depreciation related to property and equipment was $0.3 million and $0.7 million for the three and nine months ended September 30, 2022, respectively, and $0.1 million and $0.3 million for the three and nine months ended September 30, 2021, respectively.

6. Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	September 30, 2022	December 31, 2021
Advance payments to suppliers and rent deposit	$ 1,592	$ 1,499
Prepaid insurance	907	7,378
Deferred costs	51	3
VAT receivable	2,093	1,176
Other prepaid expenses	474	298
Total prepaid expenses and other current assets	$ 5,117	$ 10,354

7. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2022	December 31, 2021
Employee compensation and related benefits	$ 4,801	$ 2,309
Professional fees	4,949	3,625
Consulting and contracted research	7,968	3,925
Other	153	117
Total accrued expenses	$ 17,871	$ 9,976

8. Commitments and Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company will accrue a liability for such matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. As of September 30, 2022 and December 31, 2021, there have been no such matters identified. When only a range of possible loss can be established, the most probable amount in the range is accrued. If no amount within the range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. The Company is not currently party to any material legal proceedings.

9. Share-Based Compensation

In December 2019, the Company adopted a shareholder-approved share-based compensation plan (the “2019 Plan”), which permits the granting of incentive share options, nonqualified share options, share awards and certain other awards to its employees, members of its Board of Directors and consultants.

In connection with the IPO, the Company adopted a shareholder-approved share-based compensation plan (the “2021 Equity Plan”), which permits the granting of incentive share options, nonqualified share options, share awards and certain other awards to its employees, members of its Board of Directors and consultants. The maximum number of shares that may be delivered in satisfaction of awards under the 2021 Equity Plan was initially approximately 14.2 million shares, plus the number of shares that remained available for issuance under the 2019 Plan and that may again become available for issuance under such plan, not to exceed approximately 10.7 million shares in the aggregate, and an annual increase, to be added as of January 1st of each year from January 1, 2022, to January 1, 2031, equal to the lesser of (i) four percent (4%) of the number of shares outstanding as of such date; and (ii) the number of shares determined by the Board of Directors on or prior to such date for such year. Subsequent to the effectiveness of the 2021 Equity Plan, no additional awards have been made pursuant to the 2019 Plan. However, any outstanding awards granted under the 2019 Plan will remain outstanding, subject to the terms of the 2019 Plan and award agreements. Through September 30, 2022, there were awards outstanding for approximately 8.5 million ordinary shares under the 2019 Plan and approximately 5.5 million ordinary shares under the 2021 Equity Plan.

Share Option Awards

During the nine months ended September 30, 2022, the Company issued options to purchase a total of 464,734 ordinary shares to various employees, directors and board members with a weighted-average exercise price of $3.37 per share option and a weighted-average fair value of $2.31 per share option. The fair-value based method for valuing each share option grant on the grant date uses the Black-Scholes Model, which incorporates a number of valuation assumptions. The weighted-average fair value was estimated based on the following assumptions: risk-free interest rate of 2.56% - 3.90%; expected dividend yield of 0.00%; expected share price volatility of 76.83% - 79.65%; and expected term of 5.50 - 6.08 years.

During the nine months ended September 30, 2021 the Company issued options to purchase 3,820,173 ordinary shares with a weighted-average exercise price of $6.84 per share option and a weighted-average fair value of $3.47 per share option. The fair-value based method for valuing each share option grant on the grant date uses the Black-Scholes Model, which incorporates a number of valuation assumptions. The weighted-average fair value was estimated based on the following assumptions: risk-free interest rate of 0.09% - 1.22%; expected dividend yield of 0.00%; expected share price volatility of 60.00%; and expected term of 0.50 - 6.25 years.

As of September 30, 2022, $38.3 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 2.86 years from the date of grant. As of September 30, 2021, $18.1 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 3.36 years from the date of grant. Options granted to senior management and employees generally vest in equal annual increments over four years and grants issued subsequent to the IPO generally vest over four years with 25% vesting over the first year and monthly thereafter.

Performance Share Awards

There were no performance share awards granted during the nine months ended September 30, 2022. During the nine months ended September 30, 2021 the Company granted certain option awards with both market-vesting conditions and service-vesting conditions to a member of management. The market condition is based on the Company's enterprise value. Per the terms of the award, these options will vest in two equal tranches based on the following thresholds:

1. 50% of the performance options will vest upon satisfaction of the Company achieving an enterprise value of not less than $2.0 billion at any time after the grant date in accordance with the service condition described below.
2. 50% of the performance options will vest upon the satisfaction of the Company achieving an enterprise value of not less than $4.0 billion at any time after the grant date in accordance with the service condition described below.

The enterprise value shall be equal to the number of outstanding ordinary shares of the Company multiplied by the volume weighted average price of a single ordinary share averaged over a period of thirty days ending one day prior to the date of the valuation.

Subject to the market conditions described above, the option contains explicit service vesting conditions, with one-fourth vesting each year over four years.

The issued options are to purchase 1,938,615 ordinary shares with a weighted-average exercise price of $6.90 per share option and a weighted-average fair value of $4.72 per share option. The Company used a Monte-Carlo simulation to determine the grant date fair value for these awards, which takes into consideration the possible outcomes pertaining to the enterprise value market condition based on the following assumptions: risk-free interest rate of 0.81% - 1.63%; expected dividend yield of 0.0%; expected share price volatility of 47.07% - 80.64%; and expected term of 4.87 - 10.00 years.

As of September 30, 2022, there was $6.0 million of total unrecognized compensation cost related to outstanding performance share awards.

No performance-based share units ("PSUs") were granted during the nine months ended September 30, 2022 or 2021. As of September 30, 2022, there was $2.1 million of total unrecognized compensation cost related to outstanding PSUs.

Restricted Share Units

During the nine months ended September 30, 2022, the Company granted 29,785 non-vested restricted share units ("RSUs") to certain employees, with a weighted-average grant date fair value of $2.56 per RSU. As of September 30, 2022, there was $2.4 million of total unrecognized compensation expense related to non-vested RSUs. There were no RSUs granted during the nine months ended September 30, 2021.

During the nine months ended September 30, 2022, the Company granted 217,985 performance-based RSUs to certain employees, with a weighted-average grant date fair value of $2.17 per RSU. 60% of the total number of RSUs will vest on the one-year anniversary of the date on which the mavacamten New Drug Application ("NDA") acceptance in China is obtained. The remaining 40% of the RSUs will vest on the six-month anniversary of the date on which the mavacamten NMPA acceptance is obtained in China. Upon termination of an employee's service with the Company for any reason, any performance-based RSUs that are outstanding and not yet vested will be immediately forfeited. As of September 30, 2022, there was $1.1 million of total unrecognized compensation expense related to non-vested performance-based RSUs. There were no performance-based RSUs granted in the nine months ended September 30, 2021.

10. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of ordinary shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding, plus all additional ordinary shares that would have been outstanding, assuming dilutive potential ordinary shares had been issued for other dilutive securities. For the three and nine months ended September 30, 2022 and 2021, diluted and basic net loss per ordinary share were identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Numerator				
Net loss attributable to ordinary shareholders	$ (21,897)	$ (13,112)	$ (92,014)	$ (175,105)
Denominator				
Weighted-average shares – basic and diluted	108,353,831	20,690,908	107,854,547	20,549,310
Net loss per ordinary share – basic and diluted	$ (0.20)	$ (0.63)	$ (0.85)	$ (8.52)

The following outstanding potentially dilutive securities were excluded from the calculation of diluted net loss per share, because including them would have been anti-dilutive during each period.

	As of	
	September 30, 2022	September 30, 2021
Redeemable Convertible Preferred Shares	—	11,024,178
Employee Share Options	13,163,954	9,746,977
Non-vested restricted share units	864,050	—
QED Warrants	—	100,000
MyoKardia Warrant	170,000	170,000
Tarsus Warrants	—	125,000
Warrants in LianBio issued to QED and Tarsus	425,942	—

11. Subsequent Events

In October 2022, the Company was notified that Tarsus had achieved a certain development milestone, which, pursuant to the Tarsus License Agreement, triggered a $10.0 million milestone payment due in December 2022.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes thereto as of and for the year ended December 31, 2021 and the related management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 31, 2022. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" sections of this report and the section entitled "Risk Factors" in our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Some of the numbers included herein have been rounded for the convenience of presentation.

Overview

We are a global, science-driven biopharmaceutical company dedicated to developing and commercializing innovative medicines for patients with unmet medical needs, with an initial focus on in-licensing assets for Greater China and other Asian markets. We have assembled a pipeline of nine assets across five therapeutic areas, each with its own distinct value proposition and the potential to drive new standards of care across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications.

In November 2021, we completed an IPO of our ordinary shares through the sale and issuance of 20,312,500 American Depositary Shares ("ADSs"), at a public offering price of $16.00 per ADS. Following the closing of the IPO, on December 1, 2021, the underwriters partially exercised their option to purchase additional shares and purchased an additional 593,616 ADSs at the initial public offering price of $16.00 per ADS. We received gross proceeds of $334.5 million in connection with the IPO and subsequent exercise of the underwriters' option and aggregate net proceeds of $304.8 million after deducting underwriting discounts, commissions and other offering expenses.

The following diagram depicts our corporate structure as of September 30, 2022. As of September 30, 2022, the shares of each of our subsidiaries are 100% owned by the respective entity displayed immediately above that subsidiary. Certain warrant rights are outstanding and may be exercised in the future for equity interests in our Cayman parent entity, LianBio, and our subsidiary, Lian Cardiovascular, as described in "Note 10: Equity" in the notes to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022. Currently, our corporate structure contains no variable interest entities.

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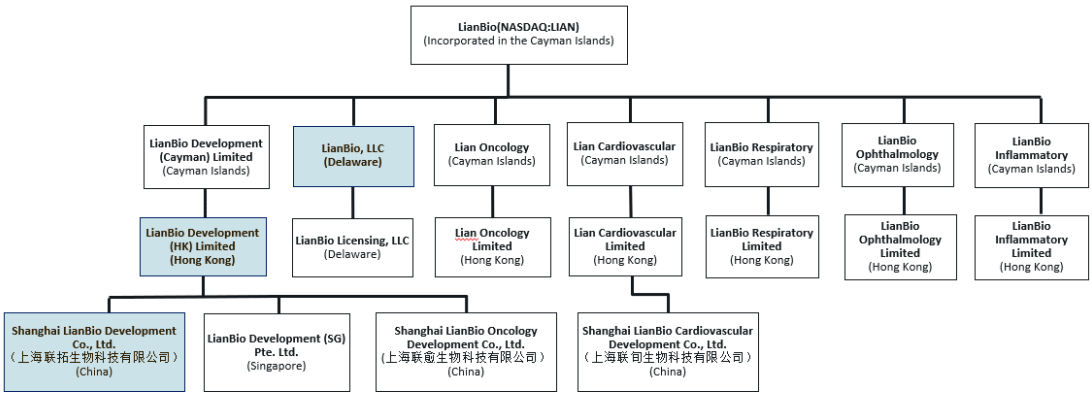

Within the organization, investor cash inflows have all been received by our parent Cayman entity, LianBio. Cash to fund our Chinese operations is transferred from our Cayman parent entity down through our Hong Kong entities and then into our Chinese entities through capital contributions. Cash to fund our operations in the United States is transferred from our Cayman parent entity down to our United States entity through a capital contribution.

Recent Business Highlights and Clinical Development Updates

Mavacamten

In August 2022, we announced that enrollment was completed in the Phase 3 EXPLORER-CN clinical trial in Chinese patients with obstructive hypertrophic cardiomyopathy. We expect to report topline results from the trial in mid-2023.

In September 2022, we collaborated with Beijing Lisheng Cardiovascular Health Foundation to launch Joy from Heart, a hypertrophic cardiomyopathy ("HCM") disease awareness campaign in China. Joy from Heart is China's first disease awareness program dedicated to improving HCM diagnosis rates and supporting HCM education initiatives for patients and healthcare providers.

TP-03

In August 2022, our partner Tarsus Pharmaceuticals, Inc. ("Tarsus") announced the initiation of a Phase 2a clinical trial of TP-03 in patients with meibomian gland disease.

In September 2022, Tarsus announced the submission of an NDA to the United States Food and Drug Administration ("FDA") for TP-03 for the treatment of *Demodex* blepharitis. Tarsus subsequently communicated that the FDA accepted the NDA with a Prescription Drug User Fee Act ("PDUFA") target action date of August 25, 2023.

In November 2022, we announced the initiation of the Phase 3 LIBRA clinical trial of TP-03 in Chinese *Demodex* blepharitis patients. We expect to report topline data from the trial in the fourth quarter of 2023.

NBTXR3

In September 2022, we announced that we began treating patients in Asia in the global Phase 3 NANORAY-312 trial evaluating NBTXR3 for the treatment of head and neck cancer.

BBP-398

In November 2022, we announced that we began treating patients in China in a Phase 1 monotherapy clinical trial of BBP-398 in patients with advanced solid tumors.

Infigratinib

In October 2022, we reported that our partner, BridgeBio Pharma, Inc. ("BridgeBio"), informed us that Helsinn Healthcare SA, which holds the Truseltiq (infigratinib) NDA in the United States, is permanently discontinuing distribution of the drug and anticipates requesting withdrawal of the NDA in the United States due to business reasons. Due to the planned withdrawal of the NDA, BridgeBio informed us that it intends to close the ongoing global Phase 3 PROOF-301 clinical trial of infigratinib in first-line cholangiocarcinoma ("CCA"). Consequently, we are terminating activities related to the PROOF-301 clinical trial in China and no longer plan to pursue development and commercialization of infigratinib in CCA indications in our licensed territories. We intend to continue to support patients who are currently being treated with infigratinib under the special pilot program implemented in the Bo'ao Lecheng pilot zone in Hainan Province. We expect to continue the ongoing Phase 2a China standalone proof of concept clinical trial of infigratinib in patients with locally advanced, metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 genetic amplification and other solid tumors with FGFR alterations. We expect to report topline data from this clinical trial in the second half of 2023.

LYR-210

In August 2022, we refined our development strategy for LYR-210. We plan to conduct a Phase 3 China standalone trial to support regulatory approval in China, leveraging the results of the ongoing Phase 3 trials of our development partner, Lyra. Lyra is expected to complete enrollment in ENLIGHTEN I, the first trial in Lyra's Phase 3 program, in mid-2023.

In September 2022, Lyra announced that it had initiated ENLIGHTEN II, the second of two global pivotal Phase 3 trials of LYR-210 in surgically naive chronic rhinosinusitis patients. In November 2022, Lyra further communicated a temporary pause in ENLIGHTEN II enrollment to align with internal manufacturing timelines for clinical trial supply.

NX-13

In August 2022, our development partner Landos Biopharma, Inc. ("Landos") announced topline results from the company's Phase 1b clinical trial of NX-13. The data showed that NX-13 was well tolerated following evaluation of multiple doses over four weeks compared with a placebo. Based on these data, Landos plans to initiate a Phase 2 clinical trial to evaluate the safety, efficacy and optimal dosing of NX-13 in patients with ulcerative colitis.

Factors Affecting Our Results of Operations

Impact of the COVID-19 pandemic on our operations

Beginning in December 2019, the outbreak of the COVID-19 pandemic created business interruptions for companies globally, including us. For example, in the biotechnology sector, companies, including our company, have experienced delays in their ability to enroll patients at clinical trial sites because of the pandemic, potentially leading to delays in the regulatory approval process. Other outbreaks may occur, or there could be further resurgences of the COVID-19 pandemic (such as current outbreaks in certain locations in China, including locations in which we are conducting clinical trials, which have led to extensive lockdowns), which have caused and could further cause business disruptions in the future.

We have been carefully monitoring the COVID-19 pandemic and its impact on our business. We have taken important steps to ensure the workplace safety of our employees when working within our administrative offices, or when traveling to our clinical trial sites. We may take further actions as may be required by federal, state or local authorities.

To date, we have been able to continue our key business activities and advance our clinical programs. However, the COVID pandemic has impacted our clinical trial enrollment and it is possible that our clinical development timelines and business plans could be adversely affected. We maintain regular communication with our vendors and clinical sites to appropriately plan for, and mitigate, the impact of the COVID-19 pandemic on our operations.

Key Components of Results of Operations

Research and development expenses

We believe our ability to successfully develop product candidates will be a significant factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investment in this area.

We expect our research and development expense to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our product candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. These expenses include:

- payments made under third party licensing and asset acquisition agreements;
- employee-related expense, including salaries, related benefits, equity-based compensation and travel expenses for employees engaged in research and development functions;
- expense incurred in connection with the clinical development of our product candidates, including expenses incurred under agreements with contract research organizations ("CROs");
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and amortization, insurance and other direct and allocated expense incurred as a result of research and development activities.

The following table sets forth the components of our research and development expenses for the periods indicated:

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Research and development expenses (in thousands):				
Licensing fees	$ —	$ —	$ 25,000	$ 136,915
Employee related expense	3,023	1,921	8,609	5,031
CRO costs	4,417	1,952	13,463	6,521
Other costs	818	782	2,106	2,571
Total	$ 8,258	$ 4,655	$ 49,178	$ 151,038

Licensing arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are generally required to make upfront payments upon entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant product candidate under these agreements, as well as tiered royalties based on net sales of the license products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our consolidated financial statements. For the three months ended September 30, 2022 and September 30, 2021, we made no upfront payments or milestone payments. For the nine months ended September 30, 2022 and September 30, 2021, we made upfront payments and milestone payments totaling $25.0 million and $136.9 million, respectively.

The following table sets forth a breakdown of licensing fees by program for the periods indicated:

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Licensing fees:				
Mavacamten	$ —	$ —	$ 5,000	$ —
BBP-398	—	—	—	8,500
Sisunatovir	—	—	—	14,000
TP-03	—	—	15,000	64,415
BT-11 and NX-13	—	—	—	18,000
NBTXR3	—	—	—	20,000
LYR-210	—	—	5,000	12,000
Total	$ —	$ —	$ 25,000	$ 136,915

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, auditing, tax services and insurance costs.

We expect that our general and administrative expenses will increase in the future to support continued development and commercialization of our product candidates. These increases will likely include increased costs related to hiring additional personnel and fees to outside consultants, attorneys and accountants, among other expenses. Additionally, we have incurred and will continue to incur increased expenses associated with being a public company, including costs of additional personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and office insurance costs, and investor and public relations costs.

Interest income, net

Interest income, net consists of interest income received on our cash balances and marketable securities and from the amortization/accretion on the premiums/discounts on marketable securities.

Other income (expense), net

Other income (expense), net consists of unrealized gains and losses on foreign currencies held in our China subsidiary, Shanghai LianBio Development Co., Ltd., unrealized foreign exchange activity from the remeasurement of our intercompany payables, bank fees incurred on our cash balances and depositary fees related to our ADSs.

Income taxes

Provision for income taxes consists of U.S. federal and state income taxes and income taxes in certain foreign jurisdictions in which we conduct business. We expect income tax expense to increase over time as the Company continues to grow net income.

We recorded income tax expense (benefit) of $0.0 million and $0.0 million for the three and nine months ended September 30, 2022 and $(0.4) million and $1.6 million for the three and nine months ended September 30, 2021, respectively.

Results of operations

Comparison of the three months ended September 30, 2022 and September 30, 2021

The following table sets forth a summary of our consolidated results of operations for the periods indicated.

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021
Operating expenses (in thousands):		
Research and development	$ 8,258	$ 4,655
General and administrative	16,291	8,889
Total operating expenses	24,549	13,544
Loss from operations	(24,549)	(13,544)
Other income:		
Interest income, net	1,405	32
Other income, net	1,253	3
Net loss before income taxes	(21,891)	(13,509)
Income taxes (benefit)	6	(397)
Net loss	$ (21,897)	$ (13,112)

Research and development expenses

Research and development expenses increased by $3.6 million from $4.7 million for the three months ended September 30, 2021 to $8.3 million for the three months ended September 30, 2022. For the three months ended September 30, 2022, research and development cost was primarily attributable to $3.0 million in personnel-related expenses and $4.4 million attributable to development activities to support our clinical trials. The remaining expense was attributable to professional fees.

For the three months ended September 30, 2021, research and development cost was primarily attributable to $1.9 million in personnel-related expenses and $2.0 million attributable to development activities to support our clinical trials. The remaining expense was attributable to professional fees.

General and administrative expenses

General and administrative expenses increased by $7.4 million from $8.9 million for the three months ended September 30, 2021 to $16.3 million for the three months ended September 30, 2022. The increase was primarily attributable to a $5.3 million increase in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and a $3.2 million increase in additional costs incurred due to operating as a publicly traded company. These increases were partially offset by a $1.1 million decrease in consulting costs.

Interest income

Interest income increased by $1.4 million from $0.0 million for the three months ended September 30, 2021 to $1.4 million for the three months ended September 30, 2022. The increase was primarily attributable to our investments in marketable securities and interest earned on cash holdings in foreign countries.

Other income, net

Other income, net increased by $1.3 million from $0.0 million for the three months ended September 30, 2021 to $1.3 million for the three months ended September 30, 2022. The increase is primarily attributable to foreign exchange gains in our foreign entities.

Income taxes (benefit)

Our income taxes (benefit) was $0.0 million, resulting in an effective income tax rate of 0.0% for the three months ended September 30, 2022. Our income tax benefit was $(0.4) million, resulting in an effective income tax rate of 2.9%, for the three months ended September 30, 2021. The variation in the effective income tax rate was primarily due to the effect of certain nonrecurring taxable income in 2021.

Comparison of the nine months ended September 30, 2022 and September 30, 2021

The following table sets forth a summary of our consolidated results of operations for the periods indicated.

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Operating expenses (in thousands):		
Research and development	$ 49,178	$ 151,038
General and administrative	46,930	22,496
Total operating expenses	96,108	173,534
Loss from operations	(96,108)	(173,534)
Other income (expense):		
Interest income, net	2,238	171
Other income (expense), net	1,873	(189)
Net loss before income taxes	(91,997)	(173,552)
Income taxes	17	1,553
Net loss	$ (92,014)	$ (175,105)

Research and development expenses

Research and development expenses decreased by $101.9 million, from $151.0 million for the nine months ended September 30, 2021 to $49.2 million for the nine months ended September 30, 2022. For the nine months ended September 30, 2022, research and development cost was primarily attributable to (i) $15.0 million related to a development milestone payment payable pursuant with the Tarsus License Agreement, (ii) $5.0 million related to a development milestone payment payable pursuant with the MyoKardia License Agreement, (iii) $5.0 million related to a development milestone payment payable pursuant with the Lyra License Agreement, (vi) $13.5 million attributable to development activities to support our clinical trials and (v) $8.6 million attributable to higher personnel-related expense, including share-based compensation expense, as a result of increased employee headcount. The remaining expense was attributable to professional fees.

For the nine months ended September 30, 2021, research and development cost was primarily attributable to (i) $55.0 million in upfront milestone payments and $9.4 million of expenses related to warrants issued in connection with the Tarsus License Agreement, (ii) a $20.0 million upfront payment pursuant to the Nanobiotix License Agreement, (iii) a $18.0 million upfront payment pursuant to the Landos License Agreement, (iv) a $14.0 million upfront payment pursuant to the ReViral License Agreement, (v) a $12.0 million upfront payment pursuant to the Lyra License Agreement, and (vi) a $8.5 million development milestone payment pursuant to the exclusive license agreement entered into with Navire. The remaining expense was attributable to higher personnel-related expenses, including share-based compensation expense, and development activities to support our clinical trials and professional fees.

General and administrative expenses

General and administrative expenses increased by $24.4 million from $22.5 million for the nine months ended September 30, 2021 to $46.9 million for the nine months ended September 30, 2022. The increase was primarily attributable to a $15.5 million increase in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount, a $9.5 million increase in additional costs incurred due to operating as a publicly traded company.

Interest income, net

Interest income, net increased by $2.1 million from $0.2 million for the nine months ended September 30, 2021 to $2.2 million for the nine months ended September 30, 2022. The increase was primarily attributable to our investments in marketable securities and interest earned on cash holdings in foreign countries.

Other income (expense), net

Other income (expense), net increased by $2.1 million from $(0.2) million for the nine months ended September 30, 2021 to $1.9 million for the nine months ended September 30, 2022. The increase was primarily attributable to depositary fees related to our ADSs and foreign exchange gains in our foreign entities.

Income taxes

Our income tax expense was $0.0 million, resulting in an effective income tax rate of 0.0% for the nine months ended September 30, 2022. Our income tax expense was $1.6 million, resulting in an effective income tax rate of (0.9)%, for the nine ended September 30, 2021. The variation in the effective income tax rate was primarily due to the effect of certain nonrecurring taxable income in 2021.

Liquidity and capital resources

Sources of liquidity

Since our incorporation, our operations have been substantially financed with proceeds from sales of preferred shares as part of the Series Seed financing, the Series A financing, the issuance of the 2020 Convertible Notes and our IPO, which was completed in November 2021. As of September 30, 2022, we had cash and cash equivalents and marketable securities of $311.7 million.

We are a holding company with no operations of our own and, as such, we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt we may incur. Deterioration in the financial condition, earnings or cash flow of our subsidiaries for any reason, as well as any changes in Chinese laws or regulations, could limit or impair their ability to pay such distributions. For additional information, see “Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations—We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business” in our Annual Report on Form 10-K for the year ended December 31, 2021.

Funding requirements

Our primary use of cash is to fund our operating expenditures, consisting of research and development expense (including activities within our clinical and regulatory initiatives and upfront and milestone payments) and general and administrative expense. Our use of cash is impacted by the timing and extent of the required payments for each of these activities.

To date, we have not generated any material revenue. We do not expect to generate revenue from the sale of our products unless and until we (i) complete development of any of our product candidates; (ii) obtain applicable regulatory approvals; and (iii) successfully commercialize or enter into collaborative agreements for our product candidates. We do not know with certainty when, or if, any of these items will ultimately occur. We expect to incur continuing significant losses for the foreseeable future and for our losses to increase as we ramp up our clinical development programs and begin activities related to commercial launch readiness. We may encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business. Moreover, since the completion of our IPO, we have incurred and will continue to incur additional costs associated with operating as a publicly traded company.

We will require additional capital to develop our product candidates and fund our operations into the foreseeable future. We anticipate that we will eventually need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the cost and timing associated with commercializing our product candidates, if they receive regulatory approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following regulatory approval;
- the impact of the COVID-19 pandemic and the Russian invasion of Ukraine on our clinical development or operations; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development and regulatory approval of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our shareholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our ordinary shares, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our shareholders.

Adequate funding may not be available to us on acceptable terms or at all. Our potential inability to raise capital when needed could have a negative impact on our financial condition and our ability to pursue our additional licensing opportunities.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented:

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net cash (used in) provided by (in thousands):		
Operating activities	$ (68,472)	$ (133,573)
Investing activities	(80,197)	(159)
Financing activities	1,710	8,249

Net cash used in operating activities

During the nine months ended September 30, 2022, operating activities used approximately $68.5 million of cash, primarily due to our net loss of $92.0 million, partially offset by non-cash consideration of $13.9 million related to share-based compensation expense, a decrease of $4.8 million for prepaid expenses and other current assets, an increase of $8.2 million for accrued expenses, and other changes related to operating assets and liabilities.

During the nine months ended September 30, 2021, operating activities used approximately $133.6 million, primarily due to our net loss of $175.1 million, partially offset by non-cash items of $9.4 million related to the warrants granted to Tarsus, $20.0 million of other receivables related to in-licensing and co-development activities related to our strategic collaboration agreement with Pfizer, $5.3 million related to share-based compensation expense, and other changes related to operating assets and liabilities.

Net cash used in investing activities

During the nine months ended September 30, 2022, investing activities used approximately $80.2 million, consisting of approximately $260.4 million for the purchases of marketable securities, and approximately $1.6 million for the purchases of property and equipment, partially offset by the sales and redemption of marketable securities of approximately $181.8 million.

During the nine months ended September 30, 2021, investing activities used approximately $0.2 million, primarily resulting from the purchases of property and equipment.

Net cash provided by financing activities

During the nine months ended September 30, 2022, financing activities provided approximately $1.7 million, primarily resulting from proceeds from the exercise of share options.

During the nine months ended September 30, 2021, financing activities provided approximately $8.2 million in net proceeds due to our issuance of Series A Preferred shares of $2.9 million and the exercise of share options of $5.3 million.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2022, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2021.

Impact of New Accounting Standards

The adoption of new accounting standards and the impact of recent accounting pronouncements not yet effective on our consolidated financial statements, if any, is discussed in Note 2 to the interim unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the period ended September 30, 2022, there were no material changes in our market risk or how our market risk is managed, compared to those disclosed under the heading "Quantitative and Qualitative Disclosures about Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2021.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation of our disclosure controls and procedures as of September 30, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings.

To the best of our knowledge, we are not currently the subject of any material governmental investigation, private lawsuit or other legal proceeding. From time to time, we may be involved in legal and regulatory proceedings or investigations concerning matters that arise in the ordinary course of our business and that could result in significant fines or penalties, have an adverse impact on our reputation, business and financial condition or results of operations and divert the attention of our management from the operation of our business. The outcome of any future litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to us. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect our business, financial condition or results of operations.

Item 1A. Risk Factors.

Information regarding risk factors appears in Part I, Item 1A, Risk Factors, in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. The Company has reviewed the risk factors, and, except as presented below, there have been no material changes in the Company's risk factors since those reported in its Annual Report on Form 10-K for the year ended December 31, 2021.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our and our partners' third-party research institution collaborators, clinical trial sites, CROs, contract manufacturing organizations ("CMOs"), suppliers and other contractors and consultants could be subject to natural or man-made disasters, public health epidemics and pandemics like the COVID-19 pandemic or other business interruptions, for which we are predominantly self-insured. The occurrence of any of these business interruptions could seriously harm our operations and financial condition and increase our costs and expenses. Through our partners, we also rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain supplies of our product candidates could be disrupted if the operations of these suppliers are affected by natural or man-made disasters, public health epidemics and pandemics, such as the COVID-19 pandemic, or other business interruptions. Damage or extended periods of interruption to our or our vendors' corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, public health epidemics, pandemics or other events could cause us to delay or cease development or commercialization of some or all of our product candidates. Although we maintain insurance coverage on our facilities, our insurance might not cover all losses under such circumstances, including damage to third-party facilities, and our business may be seriously harmed by such delays and interruption. For example, the biotechnology sector, including our company, has been impacted by the COVID-19 pandemic and could continue to experience negative impact to business operations. Other outbreaks may occur, or there could be a resurgence of the COVID-19 pandemic (including, for example, the local outbreaks and related extensive lockdowns in certain cities in China, such as Shanghai or other cities where our offices and employees are located and in which we are conducting clinical trials), which have caused and could continue to cause business disruptions.

Our or our partners' clinical development efforts have been and could be further delayed or otherwise negatively impacted, as patients are reluctant or unable to go to hospitals or clinical testing sites to receive treatment. We have experienced delays in the enrollment of patients in our clinical trials due to the pandemic. We believe our business partners have also similarly experienced delays or difficulties in enrollment of patients to their clinical trials due to the outbreak of COVID-19 in their respective territories. The ability to conduct in-person interactions between clinical and medical staff and physicians has also been adversely affected. Additionally, the clinical supply of our product candidates could be negatively impacted due to reduced operations or a shutdown of our third-party manufacturing facilities, distribution channels and transportation systems, or shortages of raw materials and drug product.

Our business and results of operations could be adversely affected by public health crises in the locations in which we, our suppliers, CROs, our licensors' CMOs and other contractors operate.

Our operations expose us to risks associated with public health crises, such as epidemics and pandemics. Our business operations and those of our and our partners' suppliers, clinical trial sites, CROs, CMOs and other contractors may potentially suffer interruptions caused by any of these events.

For example, the COVID-19 pandemic has resulted in significant governmental measures being implemented around the globe to control the spread of the virus, including quarantines, lockdowns, travel restrictions, social distancing and business shutdowns. We have taken precautionary measures intended to comply with local regulations and to help minimize the risk of the virus to our employees, such as implementing office closures, including in our China headquarters in Shanghai, and limiting non-essential travel. These measures could negatively affect our business. For instance, if certain of our employees are required to continue to work remotely as a result of local government mandates, company policy updates, or otherwise, absenteeism or employee turnover could increase, or we may experience disruptions to our operations or increased risk of a cybersecurity incident.

In response to recent outbreaks of the COVID-19 pandemic in China, the Chinese government has imposed restrictive quarantine measures, including extensive shutdowns in certain cities in China in which we operate, which have caused business disruptions. These measures, as well as other efforts and effects related to the continued COVID-19 pandemic, may continue for an indeterminate amount of time and have adversely impacted and may continue to adversely impact our and our partners' businesses, operations and financial conditions, including our or our business partners' manufacturing and supply chains, clinical trial operations and ability to advance research and development activities and pursue development of pipeline products. Each of these factors could have a material adverse impact on our business, operations and our financial results, including our ability to conduct our business in the manner and on the timelines presently planned.

The extent to which the COVID-19 pandemic may continue to impact our business will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in China and the United States and other geographies where we or our partners and our and their third-party suppliers, clinical trial sites and CMOs or CROs, or any other third parties with which we engage, operate.

As a company with substantial operations outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations, including the effects of Russia's invasion of Ukraine.

As a company with substantial operations in China, our business is subject to risks associated with conducting business outside the United States. Substantially all of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the renminbi;
- changes in a specific country's or region's political or economic environment, especially with respect to a particular country's treatment of or stance towards other countries;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad,
- including, for example, the variable tax treatment in different jurisdictions of options granted under our equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States; and
- business interruptions resulting from geopolitical actions, including war, such as the ongoing war between Russia and Ukraine, and terrorism, health epidemics and pandemics, such as the COVID-19 pandemic or natural disasters including earthquakes, typhoons, floods and fires.

For example, our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ADSs may be adversely affected by the geopolitical factors arising in connection with Russia's invasion of Ukraine. Although we do not conduct business in either Russia or Ukraine, our global operations expose us to geopolitical risks, including, in this instance, with respect to how the United States and China choose to respond to the war between Ukraine and Russia. For instance, in connection with this war, the United States and other nations have raised the possibility of secondary sanctions on China, Chinese banks and Chinese businesses that do business with Russia or its allies. We do not currently conduct business in Russia or with Russian counterparties, but we may be impacted by sanctions if third parties with which we do business, such as business partners, suppliers, intermediaries, services providers or banks, are subject to such sanctions or if broader sanctions are imposed. Our business and operations may also be adversely impacted by any actions taken by China in response to the war or any related sanctions or threatened sanctions. If this war continues or expands, or if it leads to continued political or economic instability or terrorist activity, or if it gives rise to further government actions such as sanctions or increased economic or political tensions, in particular between the United States and China, our business and financial results may be adversely impacted and the value of our ADSs may significantly decline. In addition, although we do not currently conduct any clinical trials in Russia or Ukraine, we or our partners may experience disruptions with respect to clinical trials and operations as a result of the war and its related effects, which could materially adversely impact our or their ability to conduct business, including clinical trials, in the manner and on the timelines presently planned.

Financial and capital markets volatility may adversely affect access to capital for life sciences companies including us.

Financial and capital markets are experiencing significant volatility and the volatility is adversely affecting access to capital and credit for many life sciences companies, but that risk is currently exacerbated for companies like ours with significant operations in China by factors such as the geopolitical tensions between the U.S. and China, the ongoing war between Russia and Ukraine, and the uncertainty about the duration, scope, and effect of COVID-19 restrictions. In the event that these continued adverse market conditions may affect us, we may be unable to obtain adequate capital or credit market financing, obtain that capital or credit on favorable terms, or access such capital or credit in manners most favorable to us.

We are required to obtain certain permissions from Chinese authorities to transfer certain data.

We are required to obtain approval from the Cyberspace Administration of China ("CAC") when the transfers out of mainland China of certain data that is determined to be important data or personal data falls into any of the scenarios requiring a security assessment by CAC specified in the Security Assessment Measures. The cross-border transfer out of mainland China of data requiring such a security assessment will not be allowed if the CAC does not approve the security assessment filing. In addition, the disclosure, sharing or exporting to foreign parties or entities established or actually controlled by them by a Chinese-owned entity of any data derived from human organs, tissues or cells of Chinese individuals that contain human genetic materials requires a separate notification filing to the Human Genetic Resources Administration of China ("HGRAC"). The HGRAC also requires submission of a copy of the data to be exported. If our Chinese subsidiaries intend to receive certain clinical or personal data from Chinese-owned entities or transfer certain clinical or personal data out of mainland China, they need to first evaluate whether a security assessment by CAC or a clearance from the HGRAC will be triggered by such data transfer, pass the necessary security assessment, and make the necessary notification filings for such data transfer.

If our Chinese subsidiaries do not receive or maintain approvals for such data transfers or inadvertently conclude that security assessments, approvals, or notification filings needed for such data transfers are not required, or if there are changes in applicable laws (including regulations) or interpretations of laws and our Chinese subsidiaries are required but unable to pass security assessments, obtain approvals, or make notification filings in the future, then such Chinese subsidiaries may be unable to effectuate such data transfers and this could adversely affect the operations of our Chinese subsidiaries, including limiting or prohibiting the ability of our Chinese subsidiaries to operate, and our relationships with our licensing and other collaboration partners.

We believe we will be classified as a PFIC in the current taxable year ending December 31, 2022.

We do not believe we were a PFIC for the taxable year ended December 31, 2021, but we believe we will be classified as a PFIC in the current taxable year ending December 31, 2022. We may or may not be a PFIC in subsequent years. Our actual PFIC status for any taxable year will not be determinable until after the end of such taxable year as our PFIC status is a factual determination made annually after the end of each taxable year. There can be no assurance that the IRS will agree with our determination and that the IRS would not successfully challenge our position in any taxable year. We will be a PFIC in any taxable year if at least (i) 75% of our gross income is "passive income" or (ii) 50% of the average gross value of our assets, determined on a quarterly basis, is attributable to assets that produce, or are held for the production of passive income. Because we expect to be a PFIC for our current taxable year, certain adverse U.S. federal income tax consequences could apply to U.S. persons who have acquired our ADSs or ordinary shares with respect to any "excess distribution" received from us and any gain from a sale or other disposition of our ADSs and ordinary shares.

If we are a PFIC in any taxable year in which a U.S. shareholder holds our ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. shareholder, regardless of whether we continue to meet the tests described above, unless we cease to be a PFIC and the U.S. shareholder makes the "deemed sale election".

The adverse U.S. federal income tax consequences of holding interests in a PFIC may be mitigated if the U.S. shareholder makes a valid mark-to-market election or makes valid a qualified electing fund ("QEF") election with respect to all taxable years the underlying entity is a PFIC during such U.S. shareholder's holding period or makes a purging election to cause a deemed sale of the PFIC shares at their fair market value in connection with a QEF election. We do not, however, expect to provide U.S. shareholders with the information necessary to make a valid QEF election and U.S. shareholders therefore should assume that a QEF election will not be available with respect to our ADSs or ordinary shares. Further, no assurance can be given that a mark-to-market election will be available with respect to our ADSs or ordinary shares. For additional information, see Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operation—of the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds

On October 29, 2021, our Registration Statement on Form S-1, as amended (File No. 333-259978), was declared effective in connection with our initial public offering, pursuant to which we sold an aggregate of 20,312,500 ADSs representing 20,312,500 ordinary shares, at a price to the public of $16.00 per ADS. Goldman Sachs & Co. LLC, Jefferies LLC, and BofA Securities, Inc. acted as joint lead book-running managers and Raymond James & Associates, Inc. acted as a lead manager for the offering.

Our initial public offering closed on November 3, 2021. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 2, 2021.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

Exhibit No.	Description
10.1*#	Amendment No. 1 to License and Collaboration Agreement, dated as of September 26, 2022, by and among LianBio Inflammatory Limited and Lyra Therapeutics, Inc.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Database*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

^ These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

\# Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

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 thereunto duly authorized.

LianBio

Date: November 10, 2022

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 10, 2022

By: /s/ Yi Larson

Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

FIRST AMENDMENT TO THE LICENSE AND COLLABORATION AGREEMENT

This FIRST AMENDMENT TO THE LICENSE AND COLLABORATION AGREEMENT (this "Amendment"), entered into as of September 26, 2022 (the "Amendment Effective Date"), is entered into by and between LianBio Inflammatory Limited, a company limited by shares organized and existing under the laws of Hong Kong Special Administrative Region of the People's Republic of China ("Lian"), and Lyra Therapeutics, Inc., a Delaware corporation, a Delaware corporation ("Lyra"). Lian and Lyra are each referred to herein individually as a "Party", and collectively as the "Parties."

INTRODUCTION

WHEREAS, Lian and Lyra entered into a License and Collaboration Agreement, dated May 31, 2021 (the "Agreement") for the Development, Manufacture, and Commercialization of Compounds and Licensed Products in the Field in the Territory; and

WHEREAS, the Parties wish to amend the Agreement to further clarify certain of Lian's and Lyra's Development and milestone payment commitments under the Agreement, as provided herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. Capitalized Terms. Any capitalized term used in this Amendment but not otherwise defined will have the meaning ascribed thereto in the Agreement.

2. Development Responsibilities in General. Section 3.1(a) (Development Diligence) of the Agreement is hereby deleted in its entirety and replaced as follows:

Development Diligence.

(i) Lian (directly, or through their respective Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for the Licensed Product in the Territory, and Lyra (directly, or through its respective Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to (A) complete the planned Global Phase III Trial for the Licensed Product (which Global Phase III Trial, notwithstanding any provision to the contrary set forth in Section 3.6(b) (Development Costs), Lyra will conduct at its sole cost and expense), and (B) seek and obtain Regulatory Approval for the Licensed Product in the U.S.

(ii) Unless otherwise agreed by the Parties, Lian [***] with respect to the conduct of, either of Lyra's two planned global registrational Phase III Trials for the Licensed Product, including the Global Phase III Trial (collectively, the "ENLIGHTEN Phase 3 Trials"). Following [***], and provided that [***], including [***] (collectively, the "Conditions"), Lian (directly, or through their respective Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to conduct its own independent Phase III Trial in the PRC intended to support Regulatory Approval for the Licensed Product for use in CRS in the PRC (the "China Phase III Trial") and dose the first patient in such China Phase III Trial no later than [***] following [***], and further provided

that (a) [***], the Parties will negotiate in good faith and agree to an amendment to the Territory-Specific Development Plan through the JSC in accordance with this Agreement, and (b) if [***] in compliance with all applicable Law; provided however, nothing herein shall reduce or limit Lian's diligence obligations under Section 3.1(a) (Development Diligence) to (directly, or through their respective Affiliates, Sublicensees and contractors) use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for the Licensed Product in the Territory in Indication(s) other than CRS.

(iii) Notwithstanding any provision to the contrary set forth in this Agreement, the Parties hereby agree that (A) Lian's conduct of the China Phase III Trial in lieu of its participation in the Global Phase III Trial is not a breach by Lian of any obligations under the Agreement, including Lian's diligence obligations under Section 3.1(a) (Development Diligence) of the Agreement and instead is expressly agreed by the Parties to be permitted under the terms of the Agreement; and (B) Lian will have no obligations under the Agreement (1) to participate in the Global Phase III Trial (including enrolling any Clinical Trial subjects in such Global Phase III Trial in the Territory) or (2) with respect to any costs or expenses incurred in connection with such Global Phase III Trial, all of which costs and expenses, as between the Parties, will be borne by Lyra.

3. Development Activities. Section 3.2 (Development Activities) of the Agreement is hereby deleted in its entirety and replaced with the following:

Subject to the terms and conditions of this Agreement, Lian will lead Development activities for the Licensed Product in the Territory as required to obtain, support and maintain the Regulatory Approval of the Licensed Product for CRS in the Territory. Lian will have the right to determine after considering in good faith Lyra's suggestions from which Regions all patients in any Clinical Trial for the Licensed Product conducted in the Territory are enrolled. The Parties will agree upon [***], in each case, prior to Lian's commencement of the foregoing Development activities.

4. Development Milestone Payment. Table 6.1(b) (Development Milestone Payments) of the Agreement is hereby deleted in its entirety and replaced with the following table:

Table 6.1(b) (Development Milestone Payments)	
Development Milestone Event	**Development Milestone Payment (in Dollars)**
1. [***]	[***]
1. [***]	[***]
1. [***]	[***]
1. [***]	[***]
Total	**[***]**

5. Supply Agreement. Section 4.1 (Supply Agreements) of the Agreement is hereby deleted in its entirety and replaced as follows:

(a) By [***], the Parties will negotiate in good faith and enter into a supply agreement for the Manufacture and supply of clinical quantities of Licensed Products by Lyra to Lian for use solely in connection with Clinical Trials and other Development of Licensed Products in the Field in the Territory (the "Clinical Supply Agreement").

(b) Following Lyra's receipt of Regulatory Approval for the use of the Licensed Product for CRS in the U.S., the Parties will negotiate in good faith and enter into either an addendum to the Clinical Supply Agreement or a standalone supply agreement for the Manufacture and supply of the Licensed Products to Lian to support any expanded access program, compassionate use program (including named patient program or single patient program), or other program for the supply of the Licensed Product in the Field in any Region before receipt of Regulatory Approval for Commercialization of the Licensed Product ("Pre-Approval Commercial Programs") in such Region to the extent permitted by and in accordance with applicable Laws, including any such program in the Hainan Boao Lecheng International Medical Tourism Pilot Zone, Hong Kong and Guangdong-Hong Kong-Macao Great Bay Area (the "EAP Supply Agreement"). Such Licensed Product will be in the same labeled, finished form, formulation, and dosage strength(s) that Lyra is, at such time, Manufacturing or having Manufactured for commercial use in the U.S and if such Licensed Product is sold at or below cost such supply shall be at a price equal to [***] and if such Licensed Product is sold above cost such supply shall be at a price equal to [***]. For clarity, any quantities of Licensed Products ordered by Lian but failed to be supplied or caused to be supplied by Lyra under the EAP Supply Agreement in a given Calendar Year shall not be included in determining whether a Supply Failure has occurred for such Calendar Year.

(c) No later than [***] prior to the date Lian anticipates its First Commercial Sale of the Licensed Product in the Territory, the Parties will negotiate in good faith and enter into a supply agreement for the Manufacture and supply of commercial quantities of Licensed Products by Lyra to Lian for the commercial sale and distribution of Licensed Product in the Field in the Territory (the "Commercial Supply Agreement" and, together with the Clinical Supply Agreement and the EAP Supply Agreement, the "Supply Agreements"). Unless otherwise agreed or required by applicable Laws, the Supply Agreements will specify that Lyra will (or will cause its Affiliates to) Manufacture and supply, and Lian will purchase from Lyra, all of Lian's, its Affiliates' and Sublicensees' requirements for the Licensed Products for the Development, or Commercialization (as applicable) in the Field in the Territory in their finished form and at a price equal to (a) under the Clinical Supply Agreement, [***] and (b) under the Commercial Supply Agreement, [***]; provided [***].

6. No Other Changes. All other original terms and conditions of the Agreement, except as specifically amended herein, shall remain in full force and effect. To the extent there is a conflict between this Amendment and the Agreement, the provisions of this Amendment shall control.

7. Effectiveness. This Amendment will be effective as of the Amendment Effective Date.

8. Governing Law. This Amendment will be construed in accordance with and governed by the laws of the State of New York, without regard to the conflicts of law principles thereof.

9. Severability. If any provision of this Amendment or the application thereof to any Person or circumstance will, for any reason and to any extent, be invalid or unenforceable, the remainder of this Amendment and the application of that provision to other Persons or circumstances will not be affected, but rather will be enforced to the extent permitted by applicable Law.

10. Modification. This Amendment may be amended, modified, renewed, or extended only by written instrument executed by all Parties hereto.

11. Execution in Counterparts; Facsimile Signatures. This Amendment may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

[Remainder of this page intentionally blank]

IN WITNESS WHEREOF, each Party has caused this Amendment to be duly executed by its authorized representative under seal, in duplicate on the Amendment Effective Date.

LYRA THERAPEUTICS, INC.

/s/ Maria Palasis
Name: Maria Palasis

Title: Chief Executive Officer

LIANBIO INFLAMMATORY LIMITED

/s/ Raphael Ho
Name: Raphael Ho

Title: Authorized Signatory

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yizhe Wang, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of LianBio;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yi Larson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of LianBio;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

By: /s/ Yi Larson

Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of LianBio (the "Company") for the quarterly period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Yizhe Wang, Chief Executive Officer, certify, pursuant to 18 U.S.C. Section1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2022

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of LianBio (the "Company") for the quarterly period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Yi Larson, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2022

By: /s/ Yi Larson

Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)