# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2023

OR

0 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** (State or other jurisdiction of incorporation or organization)

103 Carnegie Center Drive, Suite 309 Princeton, NJ (Address of principal executive offices)

98-1594670 (I.R.S. Employer **Identification No.)** 

08540

Registrant's telephone number, including area code: (609) 486-2308

Securities	registered pursuant to Section 12(b) o	f 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	LIAN	The Nasdaq Global Market

per share

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).

(Zip Code)

#### Yes x No 0

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	0	Accelerated filer	0
Non-accelerated filer	x	Smaller reporting company	х
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 August 7, 2023, 107,167,609 ordinary shares of the registrant, par value \$0.000017100448 per share, were outstanding, of which 42,312,215 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 2,051,410 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. We are not a Chinese operating company but are a Cayman Islands holding company with operations conducted by our subsidiaries. For more information on risks relating to our organizational structure, see "Risks Related to Doing Business in China and Our International Operations" and "Risks Related to Ownership of our Ordinary Shares or ADSs and our Status as a Public Company" in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022.

# PART I-FINANCIAL INFORMATION

# Item 1. Financial Statements

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

	June 30, 2023	]	December 31, 2022
Assets			
Current assets:			
Cash and cash equivalents	\$ 104,059	\$	79,221
Marketable securities	163,209		223,142
Prepaid expenses and other current assets	4,805		8,640
Other receivable	1,025		1,770
Total current assets	273,098		312,773
Restricted cash, non-current	69		73
Property and equipment, net	2,562		3,116
Operating lease right-of-use assets	3,049		3,978
Other non-current assets	20		20
Total assets	\$ 278,798	\$	319,960
Liabilities and Shareholders' Equity			
Current liabilities:			
Accounts payable	\$ 1,908	\$	1,453
Accrued expenses	16,879		19,826
Current portion of operating lease liabilities	1,859		1,851
Other current liabilities	996		485
Total current liabilities	 21,642		23,615
Operating lease liabilities	1,441		2,488
Other liabilities	210		210
Total liabilities	 23,293		26,313
Commitments and contingencies (Note 8)			
Shareholders' equity:			
Ordinary shares, \$0.000017100448 par value. 2,923,900,005 shares authorized as of June 30, 2023; 107,167,609 shares issued and outstanding as of June 30, 2023; 2,923,900,005 shares authorized as of December 31, 2022; 107,043,924 shares issued and outstanding as of December 31, 2022	2		2
Additional paid-in capital	741,246		732,476
Accumulated other comprehensive loss	(3,326)		(2,080)
Accumulated deficit	(516,191)		(470,525)
Total LianBio shareholders' equity	 221,731		259,873
Non-controlling interest	33,774		33,774
Total shareholders' equity	 255,505		293,647
Total liabilities and shareholders' equity	\$ 278,798	\$	319,960

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	End	ed June 30,		Six Months E	ndec	l June 30,
	 2023		2022		2023		2022
Operating expenses:							
Research and development	\$ 9,454	\$	28,591	\$	20,285	\$	40,920
General and administrative	15,590		14,551		30,728		30,639
Total operating expenses	 25,044		43,142		51,013		71,559
Loss from operations	(25,044)		(43,142)		(51,013)		(71,559)
Other income:							
Interest income, net	2,754		553		5,160		833
Other income, net	869		203		825		620
Net loss before income taxes	 (21,421)		(42,386)		(45,028)		(70,106)
Income taxes	200		5		638		11
Net loss	(21,621)		(42,391)		(45,666)		(70,117)
Other comprehensive income (loss):							
Foreign currency translation loss, net of tax	(1,641)		(421)		(1,537)		(814)
Unrealized gain (loss) on marketable securities, net of tax	(154)		(291)		291		(1,114)
Comprehensive loss	\$ (23,416)	\$	(43,103)	\$	(46,912)	\$	(72,045)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (0.20)	\$	(0.39)	\$	(0.43)	\$	(0.65)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	07,164,401	1	07,922,501	1	107,163,220	1	07,600,767

See accompanying notes to the consolidated financial statements

# LianBio Consolidated Statements of Shareholders' Equity (In thousands, except share amounts) (Unaudited)

-	Ordinar Shares	y Sha	ares Amount	Additional Paid in Capital	Com	umulated Other prehensive s) Income	Accumulated Deficit	Total LianBio Shareholders' Equity (Deficit)	Non- Controlling Interest	Total Shareholders' quity (Deficit)
Balance, December 31, 2022	107,043,924	\$	2	\$ 	\$	(2,080)	\$ (470,525)	 259,873	\$ 33,774	\$ 293,647
Share-based compensation expense	_		_	4,276		_	_	4,276	_	4,276
Issuance of restricted stock units	120,251		_	_		_	_	_	_	_
Net loss				—			(24,045)	(24,045)	_	(24,045)
Comprehensive income	—			—		549	—	549	—	549
Balance, March 31, 2023	107,164,175	\$	2	\$ 736,752	\$	(1,531)	\$ (494,570)	\$ 240,653	\$ 33,774	\$ 274,427
Share-based compensation expense	_			4,494		_		 4,494	 	 4,494
Issuance of restricted stock units	3,434					_	_	_	_	_
Net loss	—		—	—		—	(21,621)	(21,621)	—	(21,621)
Comprehensive loss						(1,795)	_	(1,795)	_	(1,795)
Balance, June 30, 2023	107,167,609	\$	2	\$ 741,246	\$	(3,326)	\$ (516,191)	\$ 221,731	\$ 33,774	\$ 255,505

-	Ordinar Shares	ry Sha	ures Amount		Additional Paid in Capital	Ot Compre	nulated her ehensive		Accumulated Deficit		Total LianBio Shareholders' Equity (Deficit)		Non- Controlling Interest	Total hareholders' juity (Deficit)
Balance, December 31, 2021	107,275,458	\$	2	\$	713,269	\$	Income 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 Income	—		—		_		(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

See accompanying notes to the consolidated financial statements

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

	Six Months Er June 30, 202			Months Ended 1ne 30, 2022
Net loss	\$ (45	5,666)	\$	(70,117)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash operating lease expense (benefit)		—		430
Depreciation expense		658		409
Share based compensation expense		3,770		9,197
Amortization of discounts on investments, net	(2	2,360)		1
Unrealized foreign currency transaction (gain) loss, net	(1	,261)		240
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	3	3,710		3,130
Other receivable		745		(1,281)
Other non-current assets		—		8
Accounts payable		476		(1,957)
Accrued expenses	(2	2,198)		7,414
Other current liabilities		273		50
Operating lease assets and liabilities, net		(97)		(32)
Net cash used in operating activities	(36	5,950)		(52,508)
Cash flows from investing activities:				
Purchase of property and equipment		(69)		(673)
Purchase of marketable securities		,806)		(126,138)
Sales and redemption of marketable securities	150	),391		85,125
Net cash provided by (used for) investing activities	62	2,516		(41,686)
Cash flows from financing activities:				
Proceeds from exercise of share options				1,710
Net cash provided by financing activities		—		1,710
Effect of exchange rate changes on cash and cash equivalents		(732)		(1,289)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 24	4,834	\$	(93,773)
Cash and cash equivalents, and restricted cash—beginning of period	79	9,294		248,182
Cash and cash equivalents, and restricted cash—ending of period	\$ 104	4,128	\$	154,409
Cash and cash equivalents—end of period	\$ 104	4,059	\$	134,334
Restricted cash—end of period	\$	69	\$	20,075
Cash and cash equivalents, and restricted cash—ending of period	\$ 104	4,128	\$	154,409
Supplemental disclosure of cash information			_	
Cash paid for income taxes	\$	3	\$	343
Supplemental disclosure of non-cash operating activities:	· · ·			
Purchase of property and equipment in accounts payable	\$	150	\$	938
· · · · · · · · · · · · · · · · · · ·	*			

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 clinical stage biopharmaceutical company dedicated to bringing innovative medicines to patients with unmet medical needs in Asia. The Company's initial focus is to license assets for development and commercialization in 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 of the Financial Accounting Standards Board.

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 June 30, 2023, and the interim consolidated statements of operations and comprehensive loss, changes in shareholders' equity for the three and six months ended June 30, 2023 and 2022, and the cash flows for the six months ended June 30, 2023 and 2022 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 six month periods are also unaudited. The interim results for the three and six months ended June 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods or any future year or period. The accompanying financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2023.

# (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, sharebased 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

The Company's operations have not been significantly impacted by the global novel coronavirus disease 2019 ("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 continue to be highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are 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 \$516.2 million as of June 30, 2023 and \$470.5 million as of December 31, 2022. The Company's cash and cash equivalents and marketable securities were \$267.3 million as of June 30, 2023 and \$302.4 as of December 31, 2022. 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, 2022. There have been no material changes to the Company's significant accounting policies during the three and six months ended June 30, 2023.

# (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 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.



# (E) Reclassification

Certain reclassifications of prior year information have been made to conform to the current year's presentation.

# **3. Material Agreements**

# License Agreement with QED Therapeutics, Inc.

In October 2019, the Company entered into a license agreement (the "QED License Agreement") with QED Therapeutics, Inc. ("QED"), as subsequently amended, 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 provided 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 was entitled to receive would have been 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. 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 midto 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). No payments were made under this agreement during the three and six months ended June 30, 2023. In August 2023, LianBio received a \$1.5 million payment under the terms of the QED License Agreement for the reimbursement of research and development costs.



# 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 provided 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 mayacamten, plus tiered royalties on net sales ranging from the low to upper-teens. The Company paid the first development milestone of \$5.0 million during the twelve months ended December 31, 2022. No payments were made under this agreement during the three and six months ended June 30, 2023.

On August 11, 2023, the Company and its wholly-owned subsidiary LianBio Licensing, LLC, Lian Cardiovascular Limited, and Shanghai LianBio Development Co., Ltd. (each, a "Lian Party", and collectively, "Lian Parties") entered into a supplemental agreement (the "nHCM Supplemental Agreement") with MyoKardia in relation to a clinical trial for mavacamten to be conducted in Mainland China for treatment of non-obstructive hypertrophic cardiomyopathy ("nHCM"). Pursuant to the nHCM Supplemental Agreement, MyoKardia will be the sponsor of a global trial with respect to mavacamten for nHCM (the "Global Clinical Study"), and will authorize and permit Shanghai LianBio Development Co., Ltd. to conduct a portion of the Global Clinical Study in Mainland China (the "China Study") in accordance with a development plan for the China Study. Lian Parties are obligated to use commercially reasonable efforts to achieve certain key milestones including enrolling in Mainland China a certain percentage of the total number of patients planned to be enrolled in the Global Clinical Study, and dosing of the first patient in the China Study within a certain period of time after the first submission of the applicable Clinical Trial Application to the applicable regulatory authority. During the term of the nHCM Supplemental Agreement, any Lian Party may effect, authorize or enter into any agreement to effect, a change of control so long as (i) the acquirer is a permissible third party acquiror that satisfies certain specified standards in the nHCM Supplemental Agreement, and (ii) the acquiror agrees in writing to be bound by the nHCM Supplemental 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 in 2021. No payments were made under this agreement during the three and six months ended June 30, 2023.

# Pfizer Strategic Collaboration

In November 2020, the Company entered into a strategic collaboration agreement (the "Pfizer Collaboration 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 Collaboration 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 and Comprehensive Loss as the services are performed.

Upon receipt in 2021, the upfront payment was recorded as restricted cash within the 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 Collaboration Agreement terminates. Under the Pfizer Collaboration 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 the Company for marketing, development and regulatory activities.

In December 2022, the Company, Pfizer, and ReViral Ltd. ("ReViral," now a wholly owned subsidiary of Pfizer) entered into a commercial agreement (the "Pfizer Commercial Agreement") with respect to sisunatovir (a fusion inhibitor product for the treatment of respiratory syncytial virus ("RSV")) as the first opted-in product under the Pfizer Collaboration Agreement. Pursuant to the Pfizer Commercial Agreement, LianBio will assign and transfer its development and commercialization rights to sisunatovir in Mainland China, Hong Kong, Macau and Singapore (the "Territory") to Pfizer.

Under the Pfizer Commercial Agreement, the \$20.0 million upfront payment, which was previously received and recorded as restricted cash, paid by Pfizer to LianBio in 2020 pursuant to the Pfizer Collaboration Agreement was released, as there are no further obligations and the associated contingencies were resolved. In addition, LianBio could also receive up to \$135.0 million in potential development and sales milestones contingent on sisunatovir achieving a specified regulatory milestone event prior to the end of October 2035 and specified net sales milestone events. LianBio is further entitled to receive tiered payments in the low single digits on a percentage of net sales of sisunatovir in the Territory. Pfizer will lead all development and commercial activities, use commercially reasonable efforts to develop and seek regulatory approval for sisunatovir as a fusion inhibitor product for treatment of RSV as a single active pharmaceutical product in Mainland China, assume all costs in the Territory, and will waive LianBio's milestone payment and royalty payment obligations previously due to ReViral pursuant to the Co-Development and License Agreement dated March 1, 2021, by and between LianBio Respiratory Limited and ReViral, which was superseded in its entirety by the Pfizer Commercial Agreement.

The Company has accounted for the Pfizer Commercial Agreement under ASC 450-30 and the consideration received under the agreement will be recognized as other income as they become realizable.

# 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 knowhow 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, 2022. 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 ("Parent Company Shares") or warrants to purchase a certain number of the Company's ordinary shares ("Parent Company Warrants") 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. Additionally, 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. During the twelve months ended December 31, 2022, the Company paid \$25.0 million to Tarsus as a result of the achievement of these milestones. No payments were made under this agreement during the three and six months ended June 30, 2023.

In February 2023, the Company entered into a clinical supply agreement (the "Tarsus Supply Agreement") with Tarsus. Upon the execution of the Tarsus Supply Agreement, Tarsus was entitled to receive a one-time payment of \$2.5 million from the Company which has been paid as of June 30, 2023.

#### 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. No payments were made under this agreement during the three and six months ended June 30, 2023.

In February 2023, the Company entered into an amendment to the Landos License Agreement, reflecting that Landos has transferred and assigned substantially all of its rights in omilancor to NImmune Biopharma, Inc ("NImmune"). As a result, the Landos License Agreement will relate only to NX-13, and the Company has entered into a direct license agreement with NImmune setting forth the terms of its continued development and commercialization of omilancor in its licensed territories. No payments were made under this agreement during the three and six months ended June 30, 2023.



# License Agreement with NImmune

In February 2023, the Company entered into a license and collaboration agreement with NImmune, under which it obtained an exclusive license with the right to sublicense to affiliates and specified third parties under certain patents and know-how of NImmune to develop, manufacture, commercialize and otherwise, make and have made, use, offer for sale, sell, have sold, and import NImmune's proprietary compound, omilancor, in the licensed regions of Mainland China, Hong Kong, Macau, Taiwan, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand and Vietnam. NImmune is entitled to receive payments from the Company totaling an aggregate of up to \$150.0 million upon the achievement of certain development and sales milestone events, up to \$45.0 million and \$105.0 million, respectively, plus tiered royalties at percentage rates ranging from the lowto the mid-teens on net sales. No payments were made under this agreement during the three and six months ended June 30, 2023.

# License Agreement with Nanobiotix

In May 2021, the Company entered into an exclusive 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. No payments were made under this agreement during the three and six months ended June 30, 2023.

#### 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. During the twelve months ended December 31, 2022, the Company paid \$5.0 million to Lyra upon the completion of the first development milestone under the Lyra License Agreement. No payments were made under this agreement during the three and six months ended June 30, 2023.

# 4. Marketable Securities and Fair Value Measurements

The following is a summary of marketable securities accounted for as available-for-sale securities at June 30, 2023 and December 31, 2022:

As of June 30, 2023 (in thousands)	Amortized Cost	G	ross Unrealized Gains	G	Fross Unrealized Losses	E	stimated Fair Value
Commercial paper	\$ 59,879	\$	2	\$	(55)	\$	59,826
Government obligations & agency securities	103,878		—		(495)		103,383
Total	\$ 163,757	\$	2	\$	(550)	\$	163,209

As of December 31, 2022 (in thousands)	Amortized Cost	G	Fross Unrealized Gains	C	Gross Unrealized Losses	]	Estimated Fair Value
Commercial paper	\$ 120,570	\$	5	\$	(313)	\$	120,262
Corporate debt securities	14,146		—		(16)		14,130
Government obligations	89,265		4		(519)		88,750
Total	\$ 223,981	\$	9	\$	(848)	\$	223,142



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 June 30, 2023 are as follows:

As of June 30, 2023 (in thousands)	Securiti	es in an unr less than 1	zed loss position nonths	Secu	rities in an unr greater thar	zed loss position months	Total				
	Unreali	zed losses	Fair Value	Unre	ealized losses	Fair Value	Unr	ealized losses		Fair Value	
Commercial paper	\$	(55)	\$ 45,394	\$	_	\$ _	\$	(55)	\$	45,394	
Government obligations & agency securities		(424)	96,641		(71)	7,236		(495)		103,877	
Total	\$	(479)	\$ 142,035	\$	(71)	\$ 7,236	\$	(550)	\$	149,271	

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, 2022 are as follows:

As of December 31, 2022 (in thousands)	Securities in an uni less than		Securities in an unr greater that		Total				
	Unrealized losses	Fair Value	Unrealized losses	Fair Value	Unrealized losses		Fair Value		
Commercial paper	\$ (313)	\$ 110,370	\$ —	\$ _	\$ (313)	\$	110,370		
Corporate debt securities	(16)	14,130	—	—	(16)		14,130		
Government obligations	(455)	 70,771	(64)	14,897	(519)		85,668		
Total	\$ (784)	\$ 195,271	\$ (64)	\$ 14,897	\$ (848)	\$	210,168		

Marketable securities on the balance sheet at June 30, 2023 and December 31, 2022 are as follows:

	June 30, 2023							
		Less than 12 Months		More Than 12 Months				
Commercial paper	\$	59,826	\$		_			
Government obligations & agency securities		96,218			7,165			
Total Marketable securities	\$	156,044	\$		7,165			

	December 31, 2022						
	Less than 12 Months	More Than 12 Months					
Commercial paper	\$ 120,262	\$					
Corporate debt securities	14,130	—					
Government obligations	70,771	17,979					
Total Marketable securities	\$ 205,163	\$ 17,979					

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 June 30, 2023 (in thousands)	Level 1	Level 2	Level 3		Total
Cash equivalents:					
Money market funds	\$ 69,061	\$ —	\$	—	\$ 69,061
Marketable securities:					
Commercial paper	—	59,826		—	59,826
Government obligations & agency securities	_	103,383		_	 103,383
Total	\$ 69,061	\$ 163,209	\$	_	\$ 232,270
As of December 31, 2022 (in					
thousands)	 Level 1	 Level 2	 Level 3		 Total
thousands) Cash equivalents:		 Level 2	 Level 3		
thousands)	\$ Level 1 11,242	\$ Level 2	\$ Level 3		\$ <b>Total</b> 11,242
thousands) Cash equivalents:	\$	\$ Level 2 —	\$ Level 3		\$
thousands) Cash equivalents: Money market funds	\$	\$ Level 2 — 120,262	\$ Level 3		\$
thousands) Cash equivalents: Money market funds Marketable securities:	\$	\$ 	\$ Level 3		\$ 11,242
thousands) Cash equivalents: Money market funds Marketable securities: Commercial paper	\$	\$ 	\$ Level 3		\$ 11,242 120,262

# 5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	June 30, 2023	]	December 31, 2022
Leasehold improvements	\$ 3,212	\$	3,372
Furniture and fixtures	113		113
Computer equipment and software	1,160		1,111
Construction in progress	187		67
	4,672		4,663
Accumulated depreciation	(2,110)		(1,547)
Total property and equipment, net	\$ 2,562	\$	3,116

Total depreciation related to property and equipment was \$0.3 million and \$0.7 million for the three and six months ended June 30, 2023, respectively, and \$0.2 million and \$0.4 million for the three and six months ended June 30, 2022, respectively.

# 6. Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	June 30, 2023	December 31, 2022
Advance payments to suppliers and rent deposit	\$ 1,921	\$ 1,957
Prepaid insurance	1,259	2,953
VAT receivable	329	2,640
Other prepaid expenses	1,296	1,090
Total prepaid expenses and other current assets	\$ 4,805	\$ 8,640

# 7. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2023	December 31, 2022
Employee compensation and related benefits	\$ 3,866	\$ 7,833
Professional fees	2,724	4,438
Consulting and contracted research	10,160	7,379
Other	129	176
Total accrued expenses	\$ 16,879	\$ 19,826

# 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 June 30, 2023 and December 31, 2022, 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 is approximately 14.2 million shares, plus the number of shares that remain 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 will be 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 June 30, 2023, there were awards outstanding for approximately 8.2 million ordinary shares under the 2019 Plan and approximately 11.8 million ordinary shares under the 2021 Equity Plan.



# Share Option Awards

Share option grants provide the right to purchase a specified number of ordinary shares from the Company at a specified price during a specified period of time. The share option exercise price per share is the fair market value of the Company's ordinary shares on the date of the grant of the share option.

During the six months ended June 30, 2023, the Company issued options to purchase a total of 4,476,836 ordinary shares to various employees, directors and board members with a weighted-average exercise price of \$2.63 per share option and a weighted-average fair value of \$1.86 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 3.53% - 3.93%; expected dividend yield of 0.00%; expected share price volatility of 78.72% - 79.25%; and expected term of 5.50 - 6.08 years.

During the six months ended June 30, 2022, the Company issued options to purchase 433,874 ordinary shares with a weighted-average exercise price of \$3.46 per share option and a weighted-average fair value of \$2.37 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% - 3.19%; expected dividend yield of 0.00%; expected share price volatility of 76.83% - 79.65%; and expected term of 5.50 - 6.08 years.

As of June 30, 2023, \$28.1 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 2.47 years from the date of grant. As of June 30, 2022, \$42.0 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 3.10 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 six months ended June 30, 2023 or 2022. As of June 30, 2023 and 2022, there was \$4.3 million and \$6.6 million of total unrecognized compensation cost related to outstanding performance share awards, respectively.

There were no performance-based share units ("PSUs") granted during the six months ended June 30, 2023 or 2022. As of June 30, 2023 and 2022, there was \$1.0 million and \$2.4 million of total unrecognized compensation cost related to outstanding PSUs.

# **Restricted Share Units**

During the six months ended June 30, 2023, the Company granted 3,007,362 non-vested restricted share units ("RSUs") to certain employees, with a weighted-average grant date fair value of \$1.74. As of June 30, 2023, there was \$6.5 million of total unrecognized compensation expense related to non-vested RSUs. During the six months ended June 30, 2022, the Company granted 24,033 RSUs with a weighted-average grant date fair value of \$2.69 per RSU. As of June 30, 2022, there was \$2.6 million of total unrecognized compensation expense related to non-vested RSUs.

During the six months ended June 30, 2023 and 2022, the company did not grant performance-based RSUs. As of June 30, 2023 and 2022, there was \$0.5 million and \$0.7 million of total unrecognized compensation expense related to non-vested performance-based RSUs.



# 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 six months ended June 30, 2023 and 2022, 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 June 30, 2023		Th	Three Months Ended June 30, 2022		Six Months Ended June 30, 2023		Months Ended June 30, 2022
Numerator								
Net loss attributable to ordinary shareholders	\$	(21,621)	\$	(42,391)	\$	(45,666)	\$	(70,117)
Denominator								
Weighted-average shares – basic and diluted		107,164,401		107,922,501		107,163,220		107,600,767
Net loss per ordinary share – basic and diluted	\$	(0.20)	\$	(0.39)	\$	(0.43)	\$	(0.65)

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	
	June 30, 2023	June 30, 2022
Employee Share Options	16,503,634	13,183,057
Non-vested restricted share units	3,546,458	641,996
MyoKardia Warrant	170,000	170,000
Warrants in LianBio issued to QED and Tarsus	425,942	425,942

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

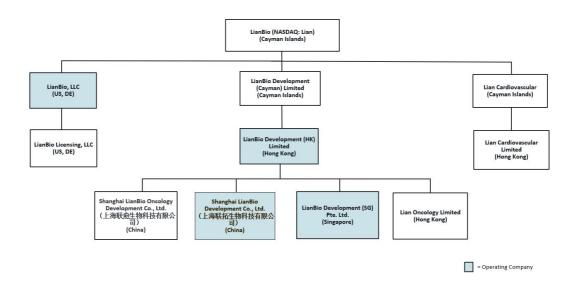
The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes thereto as of and for the year ended December 31, 2022 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 28, 2023. 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 clinical stage biopharmaceutical company dedicated to bringing innovative medicines to patients with unmet medical needs in Asia. Our initial focus is to in-license assets for development and commercialization in Greater China and other Asian markets. We have assembled a pipeline of eight therapeutic candidates across cardiovascular, oncology, ophthalmology and inflammation indications, each with its own distinct value proposition and the potential to drive new standards of care. With operations in China, Asia Pacific, and the United States, we have built a cross-border platform to provide our licensing partners access to our regulatory, development, and commercial expertise in China and other Asian markets. We have created a diverse, balanced portfolio of highly differentiated assets that represent our broad program scope and significant potential market opportunity across various stages of development, providing multiple avenues for value creation. We intend to continue to evaluate innovative, complementary product candidates with the potential to become new standards of care in Asia to deepen our pipeline.

In November 2021, we completed an initial public offering ("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 June 30, 2023. As of June 30, 2023, 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, 2022, filed with the SEC on March 28, 2023. Currently, our corporate structure contains no variable interest entities.



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 April 2023, we announced the National Medical Products Administration ("NMPA") accepted with priority review the NDA for mavacamten for the treatment of patients with obstructive hypertrophic cardiomyopathy ("oHCM").

In April 2023, we announced positive topline results from our Phase 3 EXPLORER-CN trial evaluating mavacamten in oHCM patients. EXPLORER-CN met its primary endpoint, demonstrating statistically significant and clinically meaningful improvement in Valsalva left ventricular outflow tract gradient from baseline to week 30 compared to placebo (p<0.001).

In May 2023, mavacamten was approved for the treatment of adults with symptomatic New York Heart Association Class II-III oHCM in the Macau Special Administrative Region of China.

In June 2023, mavacamten was approved for the treatment of adults with symptomatic oHCM in Singapore.

In July 2023, we announced data from the Phase 3 EXPLORER-CN trial of mavacamten in Chinese symptomatic oHCM patients were accepted for a presentation at the European Society of Cardiology ("ESC") Congress 2023.

# TP-03

In June 2023, we announced completion of enrollment in the Phase 3 LIBRA clinical trial of TP-03 in Chinese Demodex blepharitis patients. We expect the LIBRA trial to support TP-03 registration in China.

In July 2023, our partner Tarsus Pharmaceuticals announced the U.S. Food and Drug Administration's approval of TP-03 for the treatment of adults with Demodex blepharitis.

# Infigratinib

In June 2023, we announced topline results from our Phase 2a proof of concept trial evaluating infigratinib in patients with third-line or later gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 gene amplification. The trial demonstrated a confirmed objective response rate of 25.0% (n=20). The observed mediation duration of response was 3.8 months. Based on these data, the NMPA granted Breakthrough Therapy Designation to infigratinib for the treatment of gastric cancer.

# **BBP-398**

In July 2023, we announced a clinical supply agreement with AstraZeneca in China to evaluate the safety and efficacy of BBP-398, an investigational SHP2 inhibitor, in combination with AstraZeneca's osimertinib, an epidermal growth factor receptor ("EGFR") inhibitor, in a Phase 1 clinical study for the treatment of patients with non-small cell lung cancer ("NSCLC") with EGFR mutations.

In August 2023, we announced that the first patient was treated in the Phase 1 trial of BBP-398 in combination with osimertinib in Chinese NSCLC patients with EGFR mutations.

# **Corporate Developments**

In April 2023, we announced that we promoted Pascal Qian to Chief Commercial Officer. He will also continue to serve as our China General Manager.

# 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 outbreaks in certain locations in China, including locations in which we are conducting clinical trials, which 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-19 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 June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Research and development expenses (in thousands):				
Licensing fees	—	20,000	2,500	25,000
Employee related expense	2,876	2,765	5,691	5,588
CRO costs	5,600	5,343	10,279	9,046
Other costs	978	483	1,815	1,286
Total	\$ 9,454	\$ 28,591	\$ 20,285	\$ 40,920

We monitor research and development expenses associated with our clinical assets at the program level to some degree. We do not allocate employee-related expenses and other costs to specific research and development programs as these costs are deployed across multiple programs under research and development and are separately classified as unallocated research and development expenses.

The following table summarizes our research and development expenses by program for the periods indicated:

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Research and development expenses (in thousands):				
Mavacamten	1,422	6,520	3,682	8,704
Infigratinib	668	1,647	940	2,321
BBP-398	508	507	887	779
NBTXR3	1,952	988	2,754	1,457
LYR210	—	105	63	5,114
TP-03	1,499	15,490	5,165	15,796
Employee related expenses	2,876	2,765	5,691	5,588
Other costs	529	569	1,103	1,161
Total	\$ 9,454	\$ 28,591	\$ 20,285	\$ 40,920

#### 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 \$0.2 million and \$0.6 million for the three and six months ended June 30, 2023 and \$0.0 million and \$0.0 million for the three and six months ended June 30, 2022, respectively.

# **Results of Operations**

Comparison of the three months ended June 30, 2023 and 2022

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

	Three Months Ended June 30, 2023		1onths Ended e 30, 2022
Operating expenses (in thousands):			
Research and development	\$	9,454	\$ 28,591
General and administrative		15,590	14,551
Total operating expenses		25,044	 43,142
Loss from operations		(25,044)	(43,142)
Other income:			
Interest income, net		2,754	553
Other income, net		869	203
Net loss before income taxes		(21,421)	 (42,386)
Income taxes		200	5
Net loss	\$	(21,621)	\$ (42,391)

#### Research and development expenses

Research and development expenses decreased by \$19.1 million from \$28.6 million for the three months ended June 30, 2022 to \$9.5 million for the three months ended June 30, 2023. For the three months ended June 30, 2023, research and development cost was primarily attributable to (i) \$2.9 million in personnel-related expenses, including share-based compensation expense, and (ii) \$5.6 million attributable to development activities to support our clinical trials. The remaining expense was attributable to professional fees.

For the three months ended June 30, 2022, research and development cost was primarily attributable to (i) \$15.0 million related to a development milestone payment payable pursuant to our license agreement with Tarsus (the "Tarsus License Agreement"), (ii) \$5.0 million related to a development milestone payment payable pursuant with our license agreement with Myokardia (the "Myokardia License Agreement"), and (iii) \$3.3 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 \$1.0 million from \$14.6 million for the three months ended June 30, 2022 to \$15.6 million for the three months ended June 30, 2023. The increase was primarily attributable to a \$1.6 million increase in personnel-related expenses, including share-based compensation expense, for increased employee headcount. This increase was partially offset by a \$0.2 decrease in legal service costs, consulting costs and accounting services and a \$0.3 million decrease in insurance and other operating costs incurred.

#### Interest income

Interest income increased by \$2.2 million from \$0.6 million for the three months ended June 30, 2022 to \$2.8 million for the three months ended June 30, 2023. 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 \$0.7 million from \$0.2 million for the three months ended June 30, 2022 to \$0.9 million for the three months ended June 30, 2023. The increase is primarily attributable to foreign exchange gains in our foreign entities.

# Income taxes

Our income tax expense was \$0.2 million, resulting in an effective income tax rate of (0.9)%, for the three months ended June 30, 2023. Our income tax expense was \$5.0 thousand, resulting in an effective income tax rate of 0.0%, for the three months ended June 30, 2022. The variation in the effective income tax rate was primarily due to taxable income in foreign jurisdictions in 2023.

# Comparison of the six months ended June 30, 2023 and 2022

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

	Six Months Ended June 30, 2023		Six Months Ended June 30, 2022
Operating expenses (in thousands):			
Research and development	\$ 20	285	\$ 40,920
General and administrative	30	,728	30,639
Total operating expenses	51	,013	71,559
Loss from operations	(51,	013)	(71,559)
Other income:			
Interest income, net	5	160	833
Other income, net		825	620
Net loss before income taxes	(45,	028)	(70,106)
Income taxes		638	11
Net loss	\$ (45,	666)	\$ (70,117)

#### Research and development expenses

Research and development expenses decreased by \$20.6 million from \$40.9 million for the six months ended June 30, 2022 to \$20.3 million for the six months ended June 30, 2023. For the six months ended June 30, 2023, research and development cost was primarily attributable to (i) \$2.5 million related to an upfront payment related to the Tarsus Pharmaceuticals, Inc. ("Tarsus") clinical supply agreement (the "Tarsus Supply Agreement"), (ii) \$5.7 million in personnel-related expenses, including share-based compensation expense, and (iii) \$10.3 million attributable to development activities to support our clinical trials. The remaining expense was attributable to professional fees.

For the six months ended June 30, 2022, research and development cost was primarily attributable to (i) \$15.0 million related to a development milestone payment payable pursuant to 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, (iv) \$9.0 million attributable to development activities to support our clinical trials and (v) \$5.6 million attributable to higher personnel-related expenses, including share-based compensation expense, as a result of increased employee headcount. The remaining expense was attributable to professional fees.

# General and administrative expenses

General and administrative expenses increased by \$0.1 million from \$30.6 million for the six months ended June 30, 2022 and \$30.7 million for the six months ended June 30, 2023. The increase was primarily attributable to a \$3.1 million increase in personnel-related expenses, including share-based compensation expense, for increased employee headcount. This increase was partially offset by a \$2.0 million decrease in legal service costs, consulting costs and accounting services. The remaining decrease was attributable to a decrease in professional fees.



#### Interest income

Interest income increased by \$4.3 million from \$0.8 million for the six months ended June 30, 2022 to \$5.2 million for the six months ended June 30, 2023. 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 \$0.2 million from \$0.6 million for the six months ended June 30, 2022 to \$0.8 million for the six months ended June 30, 2023. The increase is primarily attributable to foreign exchange gains in our foreign entities.

# Income taxes

Our income tax expense was \$0.6 million, resulting in an effective income tax rate of (1.4)%, for the six months ended June 30, 2023. Our income tax expense was \$11.0 thousand, resulting in an effective income tax rate of 0.0%, for the six months ended June 30, 2022. The variation in the effective income tax rate was primarily due to taxable income in foreign jurisdictions in 2023.

#### 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 June 30, 2023, we had cash and cash equivalents and marketable securities of \$267.3 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, 2022.

#### 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:

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Net cash (used in) provided by (in thousands):		
Operating activities	\$ (36,950)	\$ (52,508)
Investing activities	62,516	(41,686)
Financing activities	—	1,710

# Net cash used in operating activities

During the six months ended June 30, 2023, operating activities used approximately \$37.0 million of cash, primarily due to our net loss of \$45.7 million, and non-cash consideration of \$2.4 million and \$1.3 million related to the amortization of discounts on investments and unrealized foreign currency transaction gains, respectively, partially offset by non-cash consideration of \$8.8 million related to share-based compensation expense and \$2.9 million related to changes in operating assets and liabilities.

During the six months ended June 30, 2022, operating activities used approximately \$52.5 million, primarily due to our net loss of \$70.1 million, partially offset by non-cash consideration of \$9.2 million related to share-based compensation expense and other changes related to operating assets and liabilities.



#### Net cash used in investing activities

During the six months ended June 30, 2023, investing activities provided approximately \$62.5 million, consisting of approximately \$150.4 million from the sales and redemption of marketable securities, partially offset by \$87.8 million from the purchases of marketable securities.

During the six months ended June 30, 2022, investing activities used approximately \$41.7 million, consisting of approximately \$126.1 million for purchases of marketable securities, and approximately \$0.7 million for purchases of property and equipment, partially offset by the sales and redemption of marketable securities of approximately \$85.1 million.

# Net cash provided by financing activities

During the six months ended June 30, 2023, we did not generate any net proceeds from financing activities.

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

#### 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 six months ended June 30, 2023, 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, 2022.

#### 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 June 30, 2023, 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, 2022.

# 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 June 30, 2023, 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, 2022. 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, 2022 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.

Compliance with the Data Security Law of the People's Republic of China (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the People's Republic of China (the "PIPL"), the regulations and guidelines relating to the multi-level protection scheme (the "MLPS") and any other future laws and regulations may entail significant expenses and could materially affect our business. Our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, materially and adversely impacting our operating results.

China has implemented extensive data protection, privacy and information security rules and is considering a number of additional proposals relating to these subject areas. Based on our understanding of these laws, regulations and policies, some of which were only recently enacted, and the government regulators' interpretation of those legal requirements as applied to biopharmaceutical companies like us, we believe we are compliant with all of our material legal obligations. Nevertheless, we face significant uncertainties and risks which, as explained below, may materially and adversely affect our operations.

# General risks surrounding the types of data we process and types of processing activities in which we engage

We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or anonymized health data for clinical trials in compliance with local regulations. This data could be deemed by government regulators to be "personal information," "important data," or "core data." Under the Cyber Security Law of the People's Republic of China (the "Cyber Security Law") and the Data Security Law, data categorized as core data or important data, the latter of which will be determined by governmental authorities in the form of catalogs which have not been published, is to be processed and handled with a higher level of protection, but what data constitutes core data or important data is currently not clearly defined except for certain industry sections. Therefore, in order to comply with the statutory requirements, we will need to determine whether we possess core data or important data, monitor the important data catalogs that are expected to be published by local governments and industry regulators, perform risk assessments and comply with reporting obligations to applicable regulators. We may also be required to disclose to regulators business-sensitive or network security-sensitive details regarding our processing of core data or important data.

With China's growing emphasis on its sovereignty over data derived from China, the outbound transmission of de-identified or anonymized health data for clinical trials may be subject to the new national security legal regime, including the Cyber Security Law, Data Security Law, the PIPL, the HGR Regulations and various implementing regulations and standards. Due to operational needs, we may from time to time transfer and store personal data and information outside of China in the future. Therefore, we will need to comply with the increasingly strict regulations over cross-border data transfers and monitor any new rules or regulations published by local governments and industry regulators.

Cybersecurity

The Cyber Security Law, which became effective in 2017, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that companies adopt an MLPS, under which network operators are required to perform obligations of security protection to ensure that their networks are free from interference, disruption or unauthorized access, and prevent network data on their networks from being disclosed, stolen or tampered. Under the MLPS, entities' operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which the entity's information and network systems belong, from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

Under the Cyber Security Law and Data Security Law, we are required to establish and maintain a comprehensive data and network security management system that will enable us to monitor and respond appropriately to data security and network security risks. We will need to classify and take appropriate measures to address risks created by our data processing activities and use of networks. We are obligated to notify affected individuals and appropriate Chinese regulators of and respond to any data security and network security incidents.

Establishing and maintaining such systems and complying with such requirements takes substantial time, effort, and cost, and we may not be able to establish and maintain such systems or comply with such requirements as fully as needed for compliance with our legal obligations. Despite our investment, such systems and compliance efforts may not adequately protect us or enable us to appropriately respond to or mitigate all data compliance risks or data security and network security risks or incidents we face.

# Cybersecurity review

Following the Draft Data Security Management Regulations, the Cybersecurity Review Measures, which came into effect on February 15, 2022, confirmed that critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, are required to conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review.

Pursuant to the Draft Data Security Management Regulations, data processors seeking to list on foreign stock markets shall assess their data security themselves or through data security service organizations annually, and submit the assessment reports to relevant competent authorities.

We have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator" or "online platform operator" or requiring us to go through cybersecurity review procedures by the CAC pursuant to the Cybersecurity Review Measures. Based on our understanding of the Cybersecurity Review Measures and the Draft Data Security Management Regulations, if enacted as currently proposed, we do not expect ourselves to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over Mainland China's national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information of more than one million users or individuals. However, there remains uncertainty as to how the Cybersecurity Review Measures and the Draft Data Security Management Regulations, if enacted as currently proposed, will be interpreted or implemented and whether Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Cybersecurity Review Measures and the proposed Draft Data Security Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Cybersecurity Review Measures, the Draft Data Security Management Regulations, if enacted, or other laws and regulations related to privacy, data protection and information security.

It is also unclear at the present time how widespread the cybersecurity review requirement and the enforcement action will be and what effect they will have on the life sciences sector generally and the Company in particular. Mainland China's regulators may impose penalties for non-compliance ranging from fines to suspension of operations, and this could lead to us delisting from the U.S. stock market. Currently, we have not been involved in any investigations on cybersecurity review initiated by the CAC or related governmental regulatory authorities, and we have not received any inquiry, notice, warning, or sanction in such respect.



# Cross-border data transfer requirements (security assessment; certification; standard contract)

China continues to strengthen its regulation of cross-border transfers out of Mainland China of data, including important data and personal information.

The requirement for some data processors to store personal information or important data in China, unless certain legally recognized protective measures are undertaken, was first introduced in 2017 under the Cyber Security Law, but is now solidified through the publication of the PIPL and the Security Assessment Measures. The PIPL requires that personal information processors processing certain quantities of personal information in accordance with relevant laws and regulations and need to transfer such information out of Mainland China to pass a security assessment organized by Chinese cyberspace regulators, and all other personal information processors that are not required to pass the security assessment and need to transfer out of Mainland China personal information to either: (i) undergo certification by specialized certification agencies in accordance with relevant regulations, (ii) conclude a standard contract designated by China cyberspace regulators with the overseas recipient of the personal information, or (iii) satisfy other conditions contemplated by laws, administrative regulations or Chinese cyberspace regulators. In addition to the above, personal information processors that need to transfer out of Mainland China personal information shall conduct a privacy impact assessment.

Notably, the PIPL provides for significant fines for serious violations of up to RMB 50 million, or 5% of annual revenues from the prior year and violators may also be ordered to suspend any related activity by competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or pseudonymized health data for clinical trials in compliance with local regulations. This data could be deemed as personal data or important data. We may transfer and store personal data and information that whistleblowers provide through our whistleblower hotline to, in, and using centralized databases and systems located in the United States, Mainland China, and Hong Kong. In addition, we have engaged a third-party data processor to process the personal data and information that such whistleblowers provide, on our behalf. Such personal data and information will be stored in one or more databases located on servers hosted and operated by the third party, in the United States.

To implement the security assessment mechanisms for cross-border transfers out of China of data under the Cyber Security Law, the Data Security Law, and the PIPL, the CAC promulgated the Security Assessment Measures, which took effect on September 1, 2022, and published the Security Assessment Guide on August 31, 2022. Under the Security Assessment Measures, a mandatory security assessment is required for data transfers out of Mainland China under any of the following circumstances: (i) transfer of important data by data processors; (ii) transfer of personal information by critical information infrastructure operators and data processors that process personal information of more than one million individuals; (iii) transfer of personal information by data processors that have transferred either personal information of over 100,000 individuals or sensitive personal information of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. The Security Assessment Measures have retroactive effect for relevant cross-border data transfers out of Mainland China conducted prior to September 1, 2022, and data processors are required to undergo mandatory security assessment for such prior relevant cross-border data transfers by February 28, 2023. We do not believe, based on our understanding of the Security Assessment Measures, but we may in the foreseeable future conduct cross-border data transfers of a mandatory security assessment for such prior relevant cross-border data transfers by February 28, 2023. We do not believe, based on our understanding of the Security Assessment Measures, but we may in the foreseeable future conduct cross-bord

To implement the standard contract mechanism for cross-border transfers out of China of personal information under the PIPL, on February 24, 2023, the CAC published the PRC Standard Contract, which will come into effect on June 1, 2023. Once this comes into effect, personal information processors may conclude a PRC Standard Contract with overseas recipients of personal information to comply with PIPL requirements for cross-border transfers out of Mainland China of personal information that do not need to undergo a security assessment.

To implement the personal information protection certification mechanism for cross-border transfers out of China of personal information under the PIPL, on November 4, 2022, the CAC and SAMR jointly issued the Notification on the Implementation of Personal Information Protection Certification. In parallel, on December 16, 2022, the National Information Security Standardization Technical Committee released an updated version of the Certification Specification which provides the general principles and detailed requirements for personal information processors engaging in the cross-border transfer out of Mainland China of personal information to meet in order to obtain a personal information protection certification from qualified certification institutions for cross-border transfers out of China of personal information governed by the PIPL.

Transferring data to foreign law enforcement agencies or judicial authorities



The Data Security Law and PIPL prohibit entities in Mainland China from transferring data (including personal information) stored in Mainland China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. We may need to pass a government security review or obtain government approval in order to share data (including personal information) stored in Mainland China with judicial and law enforcement authorities outside of Mainland China. Therefore, if judicial and law enforcement authorities outside Mainland China require us to provide data stored in Mainland China, and we are not able to pass any required government security review or obtain any required government approval to do so, we may not be able to meet the foreign authorities' requirements. The potential conflicts in legal obligations could have adverse impacts on our operations in and outside of Mainland China. Recently, the CAC has taken action against several Chinese internet companies listed on U.S. securities exchanges for alleged national security risks and improper collection and use of the personal information of Chinese data subjects. According to the official announcement, the action was initiated based on the National Security Law of the People's Republic of China (the "National Security Law"), the Cyber Security Law and the Cybersecurity Review Measures, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests."

#### Industry and local regulations

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in Mainland China. For example, the HGR Regulation prohibits both onshore and offshore entities established or actually controlled by foreign entities and individuals from collecting or biobanking any China-Sourced HGR in China, as well as providing such China-Sourced HGR outside of China. Chinese parties are required to seek an advance approval for the collection and biobanking of all China-Sourced HGR. Approval for any export or cross-border transfer of China-Sourced HGR in the form of biospecimens is required, and transfer of derived data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data with the Human Genetic Resources Administration of China (the "HGRAC") for record purposes and to obtain a notification filing number in order to transfer the data. The HGR Regulation also requires that foreign parties or entities established or actually controlled by them ensure the full participation of Chinese parties in international collaborations and share all records and data with the Chinese parties.

To further tighten the control of China-Sourced HGR, the SCNPC issued the Eleventh Amendment to the Criminal Law of the People's Republic of China on December 26, 2020, which became effective on March 1, 2021, criminalizing the illegal collection of China-Sourced HGR and the illegal transfer of China-sourced biospecimens outside of Mainland China. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to seven years and/or a criminal fine. In October 2020, the SCNPC adopted the Biosecurity Law, which became effective on April 15, 2021. The Biosecurity Law will establish an integrated system to regulate biosecurity-related activities in Mainland China, including, among others, the security regulation of HGR and biological resources. The Biosecurity Law for the first time expressly declared that Mainland China has sovereignty over its HGR, and further endorsed the HGR Regulation by recognizing the fundamental regulatory principles and systems established by it over the utilization of China-Sourced HGR by foreign parties or entities established or actually controlled by them in Mainland China. Though the Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by Mainland China's highest legislative authority, it gives Mainland China's primary regulator of HGR, the MOST, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for China-Sourced HGR will evolve and become even more rigorous and sophisticated. In addition, the interpretation and application of data protection laws in Mainland China and elsewhere are often uncertain and in flux. In May 2023, the Ministry of Science and Technology, or MOST, published the Implementing Rules of the HGR Regulation (the "HGR Implementing Rules") which came into effect in July 2023. The HGR Implementing Rules have, among other things, provided operational details and clarified questions that have emerged in the past few years, such as further clarified the scope of China-Sourced HGR, improved the procedure rules for applicable approval, filing and security review, and refined the provisions with respect to the prohibition on the collection, preservation and export of China-Sourced HGR by foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals. Under the HGR Implementing Rules, clinical studies conducted for the purpose of obtaining marketing authorization for drugs and medical devices in China, if not involving the export of human genetic materials, will be eligible for a notification filing (instead of the advance approval) if the human genetic materials are collected by sites, and processed by sites or an onshore third-party specified in the clinical trial protocol. The HGR Implementing Rules also enumerate situations where a security review is required for external provision of or open access to of human genetic data, such as external provision of or open access to human genetic data about important genetic pedigrees, human genetic data from specific regions, and exome sequencing and genome sequencing information of over 500 individuals.

So far, the HGRAC has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain biospecimens to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant human genetic materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAC to take rectification measures and was also banned by the HGRAC from submitting any clinical trial applications until the HGRAC was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in Mainland China until the ban was lifted. In another case, the CRO engaged by the Chinese subsidiary of a multinational pharmaceutical company was found to have forged an ethics committee approval in order to accelerate the HGRAC approval. Both the Chinese subsidiary of the multi-national pharmaceutical company and the CRO were debarred from initiating new applications for a period of 6 to 12 months, respectively.

# Uncertainties about our compliance with the changing legal landscape despite our best efforts

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with the Cyber Security Law, the Data Security Law, the PIPL and other related laws and regulations could significantly increase the cost to us of providing our products, require significant changes to our operations or even prevent us from providing certain products in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, products or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law, the PIPL and/or related laws and regulations. Any failure on our part to comply with such laws or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our business, financial condition and results of operations. If the Chinese parties fail to comply with data protection, data privacy and cybersecurity laws, regulations and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately or destroyed, we may lose our confidential information and be subject to litigation and government enforcement actions. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or delays in the initiation of new trials, delays in sharing or an inability to share or receive clinical trial data with or from our collaborators, confiscation of China-Sourced HGR, administrative fines, disgorgement of illegal gains, or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further clinical trials and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in Mainland China. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the PIPL, the Cyber Security Law, the Cybersecurity Review Measures and the recent Chinese government actions could materially adversely affect our ability, on favorable terms, to raise capital in the U.S. market in the future.

The national security legal regime imposes stricter data localization requirements on personal information and human health-related data and requires us to undergo cybersecurity or other security review and assessments, obtain government approval or certification, implement technical and organizational measures for data privacy and protection, conduct privacy impact assessments, or put in place certain contractual protections before transferring personal information and human health-related data out of Mainland China. As a result, personal information, important data and health and medical data that we or our customers, vendors, clinical trial sites, pharmaceutical partners and other third parties collect, generate or process in Mainland China may be subject to such data localization requirements and heightened regulatory oversight and controls. We may need to maintain local data centers in Mainland China, enter into standard contracts with the overseas recipients of any personal information processed by us, conduct privacy impact assessments, undergo security assessments, or obtain the requisite approvals from the Chinese government for the transmission outside of Mainland China of such controlled information and data, which could significantly increase our operating costs or cause delays or disruptions in our business operations in and outside Mainland China. We expect that the evolving regulatory interpretation and enforcement of the national security legal regime will lead to increased operational and compliance costs and will require us to continually monitor and, where necessary, make changes to our operations, policies, and procedures. If our operations, or the operations of our CROs, licensees or partners, are found to be in violation of these requirements, we may suffer loss of use of data, suffer a delay in obtaining regulatory approval for our products, be unable to transfer data out of Mainland China, be unable to comply with our contractual requirements, suffer reputational harm, or be subject to penalties, including administrative, civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations. If any of these were to occur, it could materially adversely affect our ability to operate our business and our financial results.

#### 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 IPO, 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 IPO closed on November 3, 2021. There has been no material change in the planned use of proceeds from our IPO 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.

On August 11, 2023, we and our wholly-owned subsidiary LianBio Licensing, LLC, Lian Cardiovascular Limited, and Shanghai LianBio Development Co., Ltd. (each, a "Lian Party", and collectively, "Lian Parties") entered into a supplemental agreement (the "nHCM Supplemental Agreement") with MyoKardia Inc. ("MyoKardia," now a wholly-owned subsidiary of Bristol-Myers Squibb), in relation to a clinical trial for mavacamten to be conducted in Mainland China for treatment of non-obstructive hypertrophic cardiomyopathy ("nHCM"). Pursuant to the nHCM Supplemental Agreement, MyoKardia will be the sponsor of a global trial with respect to mavacamten for nHCM (the "Global Clinical Study"), and will authorize and permit Shanghai LianBio Development Co., Ltd. to conduct a portion of the Global Clinical Study in Mainland China (the "China Study") in accordance with a development plan for the China Study. Lian Parties are obligated to use commercially reasonable efforts to achieve certain key milestones including enrolling in Mainland China a certain percentage of the total number of patients planned to be enrolled in the Global Clinical Study, and dosing of the first patient in the China Study within a certain percentage of the total number of patients planned to be enrolled in the Global Clinical Study, and dosing of the first patient in the China Study within a certain percentage of the total number of patients planned to be enrolled in the Global Clinical Study, and dosing of the first patient in the China Study within a certain percentage of the total number of patients planned to be enrolled in the Global Clinical Study, and dosing of the first patient in the China Study within a certain percentage of the total number of patterns price a charge of control so long as (i) the acquirer is a permissible third party acquiror that satisfies certain specified standards in the nHCM Supplemental Agreement, and (ii) the acquirer agreement is a permissible third party acquiror that satisfies certain specified standards in the nHCM Sup

# 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
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

By:

Date: August 14, 2023

/s/ Yizhe Wang

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

Date: August 14, 2023

By:

/s/ Yi Larson

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

#### 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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: August 14, 2023

By:

/s/ Yizhe Wang

Yizhe Wang Chief Executive Officer (Principal Executive Officer)

#### 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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: August 14, 2023

By:

/s/ Yi Larson

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

# 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 June 30, 2023 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: August 14, 2023

By:

/s/ Yizhe Wang

Yizhe Wang Chief Executive Officer (Principal Executive Officer)

# 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 June 30, 2023 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: August 14, 2023

By:

/s/ Yi Larson **Yi Larson** 

Chief Financial Officer (Principal Financial and Accounting Officer)