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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40947

LianBio

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**98-1594670**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
103 Carnegie Center Drive, Suite 309 Princeton, NJ	**08540**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 1 ordinary share, par value $0.000017100448 per share	**LIAN**	**The Nasdaq Global Market**

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

As of November 9, 2023, 108,062,638 ordinary shares of the registrant, par value $0.000017100448 per share, were outstanding, of which 43,207,244 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 1,156,381 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 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;
- our Board of Directors' comprehensive strategic review of the Company; 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 103,457	$ 79,221
Marketable securities	148,765	223,142
Prepaid expenses and other current assets	4,673	8,640
Other receivable	910	1,770
Total current assets	257,805	312,773
Restricted cash, non-current	69	73
Property and equipment, net	2,364	3,116
Operating lease right-of-use assets	2,644	3,978
Other non-current assets	20	20
Total assets	$ 262,902	$ 319,960
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 6,229	$ 1,453
Accrued expenses	15,882	19,826
Current portion of operating lease liabilities	1,893	1,851
Other current liabilities	1,623	485
Total current liabilities	25,627	23,615
Operating lease liabilities	950	2,488
Other liabilities	213	210
Total liabilities	$ 26,790	$ 26,313
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Ordinary shares, $0.000017100448 par value. 2,923,900,005 shares authorized as of September 30, 2023; 107,168,686 shares issued and outstanding as of September 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	745,786	732,476
Accumulated other comprehensive loss	(3,220)	(2,080)
Accumulated deficit	(540,230)	(470,525)
Total LianBio shareholders' equity	202,338	259,873
Non-controlling interest	33,774	33,774
Total shareholders' equity	236,112	293,647
Total liabilities and shareholders' equity	$ 262,902	$ 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 Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 9,018	$ 8,258	$ 29,303	$49,178
General and administrative	17,283	16,291	48,011	46,930
Total operating expenses	26,301	24,549	77,314	96,108
Loss from operations	(26,301)	(24,549)	(77,314)	(96,108)
Other income:				
Interest income, net	2,707	1,405	7,867	2,238
Other income, net	141	1,253	966	1,873
Net loss before income taxes	(23,453)	(21,891)	(68,481)	(91,997)
Income taxes	586	6	1,224	17
Net loss	(24,039)	(21,897)	(69,705)	(92,014)
Other comprehensive income (loss):				
Foreign currency translation loss, net of tax	(130)	(2,282)	(1,667)	(3,096)
Unrealized gain (loss) on marketable securities, net of tax	236	(160)	527	(1,274)
Comprehensive loss	$ (23,933)	$ (24,339)	$ (70,845)	$ (96,384)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.22)	$ (0.20)	$ (0.65)	$ (0.85)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	107,167,691	108,353,831	107,164,699	107,854,547

See accompanying notes to the consolidated financial statements

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

	Ordinary Shares		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total LianBio Shareholders' Equity (Deficit)	Non-Controlling Interest	Total Shareholders' Equity (Deficit)
	Shares	Amount						
Balance, December 31, 2022	107,043,924	$ 2	$ 732,476	$ (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
Share-based compensation expense	—	—	4,540	—	—	4,540	—	4,540
Issuance of restricted stock units	1,077	—	—	—	—	—	—	—
Net loss	—	—	—	—	(24,039)	(24,039)	—	(24,039)
Comprehensive loss	—	—	—	106	—	106	—	106
Balance, September 30, 2023	107,168,686	$ 2	$ 745,786	$ (3,220)	$ (540,230)	$ 202,338	$ 33,774	$ 236,112

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

	Ordinary Shares		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total LianBio Shareholders' Equity (Deficit)	Non-Controlling Interest	Total Shareholders' Equity (Deficit)
	Shares	Amount						
Balance, December 31, 2021	107,275,458	$ 2	$ 713,269	$ 526	$ (360,235)	$ 353,562	$ 33,774	$ 387,336
Share-based compensation expense	—	—	4,669	—	—	4,669	—	4,669
Receivable from related party	—	—	1,710	—	—	1,710	—	1,710
Net loss	—	—	—	—	(27,726)	(27,726)	—	(27,726)
Comprehensive 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
Share-based compensation expense	—	—	4,739	—	—	4,739	—	4,739
Net Loss	—	—	—	—	(21,897)	(21,897)	—	(21,897)
Comprehensive Loss	—	—	—	(2,442)	—	(2,442)	—	(2,442)
Balance, September 30, 2022	108,353,831	$ 2	$ 728,915	$ (3,844)	$ (452,249)	$ 272,824	$ 33,774	$ 306,598

See accompanying notes to the consolidated financial statements

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Net loss	$ (69,705)	$ (92,014)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash operating lease expense	—	354
Depreciation expense	983	689
Share based compensation expense	13,310	13,936
Amortization of discounts on investments, net	(3,368)	(481)
Unrealized foreign currency transaction gain, net	(1,206)	(1,375)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,663	4,794
Other receivable	860	(1,244)
Other non-current assets	—	11
Accounts payable	4,949	(1,091)
Accrued expenses	(3,375)	8,197
Other current liabilities	1,186	(248)
Operating lease assets and liabilities, net	(111)	—
Net cash used in operating activities	(52,814)	(68,472)
Cash flows from investing activities:		
Purchase of property and equipment	(229)	(1,610)
Purchase of marketable securities	(128,118)	(260,367)
Sales and redemption of marketable securities	206,391	181,780
Net cash provided by (used for) investing activities	78,044	(80,197)
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	(998)	(2,291)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 24,232	$ (149,250)
Cash and cash equivalents, and restricted cash—beginning of period	79,294	248,182
Cash and cash equivalents, and restricted cash—end of period	$ 103,526	$ 98,932
Cash and cash equivalents—end of period	$ 103,457	$ 78,862
Restricted cash—end of period	$ 69	$ 20,070
Cash and cash equivalents, and restricted cash—end of period	$ 103,526	$ 98,932
Supplemental disclosure of cash information		
Cash paid for income taxes	$ 17	$ 523
Supplemental disclosure of non-cash operating activities:		
Purchase of property and equipment in accounts payable	$ 133	$ 551

See accompanying notes to the consolidated financial statements

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

1. Nature of Business

LianBio ("LianBio" or the "Company") is a 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 September 30, 2023, and the interim consolidated statements of operations and comprehensive loss, changes in shareholders' equity for the three and nine months ended September 30, 2023 and 2022, and the cash flows for the nine months ended September 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 nine month periods are also unaudited. The interim results for the three and nine months ended September 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, share-based compensation, and share options. Actual results could differ from those used in evaluating these accounting estimates.

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

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 $540.2 million as of September 30, 2023 and $470.5 million as of December 31, 2022. The Company's cash and cash equivalents and marketable securities were $252.2 million as of September 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 nine months ended September 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 and, as a result, the Company will comply with new or revised accounting standards on the same timeline as other public companies. The Company has evaluated recent accounting pronouncements and believes that there are none that will have a material impact on its financial position or results of operations upon adoption.

(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 mid- to high-teens on the net sales of the licensed products, or (b) the applicable rate payable under QED's agreement with its upstream licensor (capped in the mid-teens). No payments were made under this agreement during the three and nine months ended September 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, and the number of Parent Company Shares under the Parent Company Warrant that 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, continued to hold its warrant to purchase 170,000 ordinary shares in Lian Cardiovascular. MyoKardia's option to convert the warrant irrevocably terminated upon the completion of the Company's IPO. Additionally, MyoKardia was entitled to receive a nonrefundable financing milestone payment of $35.0 million upon a specified financing event, which occurred on October 29, 2020. The financing milestone was recorded at present value upon execution of the MyoKardia License Agreement, with total imputed interest of $2.3 million accreted under the effective interest method through the date the liability was settled. The financing milestone was paid to MyoKardia in December 2020 as a result of the Series A Preferred financing. Additionally, MyoKardia is entitled to receive from the Company development milestone payments of up to $60.0 million upon achievement of specified development milestones, and sales milestone payments of up to $87.5 million based on cumulative net sales of mavacamten, plus tiered double-digit royalties on net sales. 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 nine months ended September 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, (ii) the acquiror agrees in writing to be bound by the nHCM Supplemental Agreement and the MyoKardia License Agreement, and (iii) in the event an acquirer engaged in any competing program, it will implement reasonable firewall safeguards..

On October 24, 2023 (the "Termination Effective Date"), the Company entered into a Termination Agreement, (the "Termination Agreement"), by and among MyoKardia and BMS (the "Licensor Parties") and, as applicable, E.R. Squibb Co. & Sons, L.L.C. and Swords Laboratories Unlimited Company, on the one hand, and the Company, Lian Cardiovascular, Lian Cardiovascular Limited, LianBio Development (HK) Limited, LianBio Licensing, LLC and Shanghai LianBio Development Co., Ltd. (collectively, the "Licensee Parties"), on the other hand. Pursuant to the Termination Agreement, the Company terminated the MyoKardia License Agreement. The Company received a one-time payment of $350 million as consideration for terminating the MyoKardia License Agreement and certain ancillary agreements, including the nHCM Supplemental Agreement and the Warrant, and was released from expected payment obligations of $127.5 million in remaining milestone payments under the MyoKardia License Agreement.

Pursuant to the Termination Agreement, the Licensee Parties will perform certain transition activities to facilitate the transition of development and commercialization of mavacamten in the applicable territories to the Licensor Parties, including assignment, transfer and transition of certain related rights, agreements, documents, filings and studies as well as certain ongoing regulatory activities and support related to mavacamten during the transition period, as applicable. The transition activities are expected to be completed within 18 months following the Termination Effective Date.

In addition, the Licensor Parties will reimburse the Licensee Parties for certain costs and expenses incurred in the performance of transition activities, for certain personnel costs and for amounts that become due under certain agreements following the Termination Effective Date.

The Termination Agreement further provides that certain employees of the Licensee Parties or their affiliates who are working on the development and commercialization of mavacamten will receive offers of employment from entities designated by the Licensor Parties.

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 nine months ended September 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 know-how to develop, manufacture and commercialize TP-03 for the treatment of patients with Demodex blepharitis and Meibomian Gland Disease in Mainland China, Macau, Hong Kong and Taiwan. Under the license agreement, Tarsus received a nonrefundable upfront payment of $15.0 million and was granted three warrants to purchase 125,000 ordinary shares in Lian Ophthalmology, a subsidiary of LianBio, valued at $9.4 million (the "Tarsus Warrants"). Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model and the underlying assumptions are discussed in further detail in Note 10 in the Company's Annual Report on Form 10-K for the year ended December 31, 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 nine months ended September 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 September 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 nine months ended September 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 nine months ended September 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 low- to the mid-teens on net sales. No payments were made under this agreement during the three and nine months ended September 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 nine months ended September 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 nine months ended September 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 September 30, 2023 and December 31, 2022:

As of September 30, 2023 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 35,070	$ —	$ (26)	$ 35,044
Corporate debt securities	17,222	—	(6)	17,216
Government obligations & agency securities	96,785	—	(280)	96,505
Total	$ 149,077	$ —	$ (312)	$ 148,765

As of December 31, 2022 (in thousands)	Amortized Cost	Gross Unrealized Gains	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 September 30, 2023 are as follows:

As of September 30, 2023 (in thousands)	Securities in an unrealized loss position less than 12 months		Securities in an unrealized loss position greater than 12 months		Total	
	Unrealized losses	Fair Value	Unrealized losses	Fair Value	Unrealized losses	Fair Value
Commercial paper	$ (26)	$ 35,044	$ —	$ —	$ (26)	$ 35,044
Corporate debt securities	(6)	17,216	—	—	(6)	17,216
Government obligations & agency securities	(280)	96,505	—	—	(280)	96,505
Total	$ (312)	$ 148,765	$ —	$ —	$ (312)	$ 148,765

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 unrealized loss position less than 12 months		Securities in an unrealized loss position greater than 12 months		Total	
	Unrealized losses	Fair Value	Unrealized losses	Fair Value	Unrealized losses	Fair Value
Commercial paper	$ (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 September 30, 2023 and December 31, 2022 are as follows:

	September 30, 2023	
	Less than 12 Months	More Than 12 Months
Commercial paper	$ 35,044	$ —
Corporate debt securities	17,216	—
Government obligations & agency securities	96,505	—
Total Marketable securities	$ 148,765	$ —

	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 September 30, 2023 (in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 5,825	$ —	$ —	$ 5,825
Marketable securities:				
Commercial paper	—	35,044	—	35,044
Corporate debt securities	—	17,216	—	17,216
Government obligations & agency securities	—	96,505	—	96,505
Total	$ 5,825	$ 148,765	$ —	$ 154,590

As of December 31, 2022 (in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 11,242	$ —	$ —	$ 11,242
Marketable securities:				
Commercial paper	—	120,262	—	120,262
Corporate debt securities	—	14,130	—	14,130
Government obligations	—	88,750	—	88,750
Total	$ 11,242	$ 223,142	$ —	$ 234,384

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2023	December 31, 2022
Leasehold improvements	$ 3,195	$ 3,372
Furniture and fixtures	112	113
Computer equipment and software	1,429	1,111
Construction in progress	50	67
	4,786	4,663
Accumulated depreciation	(2,422)	(1,547)
Total property and equipment, net	$ 2,364	$ 3,116

Total depreciation related to property and equipment was $0.3 million and $1.0 million for the three and nine months ended September 30, 2023, respectively, and $0.2 million and $0.7 million for the three and nine months ended September 30, 2022, respectively.

6. Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	September 30, 2023	December 31, 2022
Advance payments to suppliers and rent deposit	$ 1,858	$ 1,957
Prepaid insurance	496	2,953
VAT receivable	901	2,640
Other prepaid expenses	1,418	1,090
Total prepaid expenses and other current assets	$ 4,673	$ 8,640

7. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2023	December 31, 2022
Employee compensation and related benefits	$ 5,416	$ 7,833
Professional fees	2,428	4,438
Consulting and contracted research	7,795	7,379
Other	243	176
Total accrued expenses	$ 15,882	$ 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 September 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 September 30, 2023, there were awards outstanding for approximately 8.1 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 nine months ended September 30, 2023, the Company issued options to purchase a total of 4,521,140 ordinary shares to various employees, directors and board members with a weighted-average exercise price of $2.62 per share option and a weighted-average fair value of $1.85 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% - 4.61%; expected dividend yield of 0.00%; expected share price volatility of 78.61% - 79.25%; and expected term of 5.50 - 6.08 years.

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

As of September 30, 2023, $25.0 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 2.25 years from the date of grant. As of September 30, 2022, $38.3 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 2.86 years from the date of grant. Options granted to senior management and employees generally vest in equal annual increments over four years and grants issued subsequent to the IPO generally vest over four years with 25% vesting over the first year and monthly thereafter.

Performance Share Awards

There were no performance share awards granted during the nine months ended September 30, 2023 or 2022. As of September 30, 2023 and 2022, there was $3.7 million and $6.0 million of total unrecognized compensation cost related to outstanding performance share awards, respectively.

There were no performance-based share units ("PSUs") granted during the nine months ended September 30, 2023 or 2022. As of September 30, 2023 and 2022, there was $0.8 million and $2.1 million of total unrecognized compensation cost related to outstanding PSUs.

Restricted Share Units

During the nine months ended September 30, 2023, the Company granted 3,038,474 non-vested restricted share units ("RSUs") to certain employees, with a weighted-average grant date fair value of $1.74. As of September 30, 2023, there was $6.0 million of total unrecognized compensation expense related to non-vested RSUs. During the nine months ended September 30, 2022, the Company granted 29,785 RSUs with a weighted-average grant date fair value of $2.56 per RSU. As of September 30, 2022, there was $2.4 million of total unrecognized compensation expense related to non-vested RSUs.

During the nine months ended September 30, 2023 and 2022, the Company did not grant performance-based RSUs. As of September 30, 2023 and 2022, there was $0.4 million and $1.1 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 nine months ended September 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 September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Numerator				
Net loss attributable to ordinary shareholders	$ (24,039)	$ (21,897)	$ (69,705)	$ (92,014)
Denominator				
Weighted-average shares – basic and diluted	107,167,691	108,353,831	107,164,699	107,854,547
Net loss per ordinary share – basic and diluted	$ (0.22)	$ (0.20)	$ (0.65)	$ (0.85)

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

	As of	
	September 30, 2023	September 30, 2022
Employee Share Options	16,309,531	13,163,954
Non-vested restricted share units	3,565,847	864,050
MyoKardia Warrant	170,000	170,000
Warrants in LianBio issued to QED and Tarsus	425,942	425,942

11. Subsequent Event

On October 24, 2023, the Company entered into the Termination Agreement. Pursuant to the Termination Agreement, the Company terminated the MyoKardia License Agreement. The Company received a one-time payment of $350 million as consideration for terminating the MyoKardia License Agreement and certain ancillary agreements, and were released from expected payment obligations of $127.5 million in remaining milestone payments under the MyoKardia License Agreement.

Pursuant to the Termination Agreement, the Licensee Parties will perform certain transition activities to facilitate the transition of development and commercialization of mavacamten in the applicable territories to the Licensor Parties, including assignment, transfer and transition of certain related rights, agreements, documents, filings and studies as well as certain ongoing regulatory activities and support related to mavacamten during the transition period, as applicable. The transition activities are expected to be completed within 18 months following the Termination Effective Date.

In addition, the Licensor Parties will reimburse the Licensee Parties for certain costs and expenses incurred in the performance of transition activities, for certain personnel costs and for amounts that become due under certain agreements following the Termination Effective Date.

The Termination Agreement further provides that certain employees of the Licensee Parties or their affiliates who are working on the development and commercialization of mavacamten will receive offers of employment from entities designated by the Licensor Parties.

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

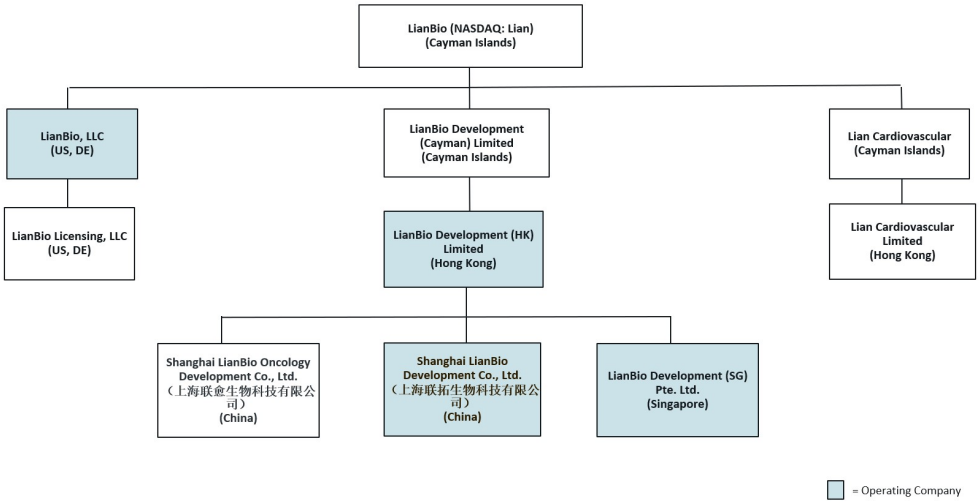
The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements 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 a pipeline of seven therapeutic candidates across 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 September 30, 2023. As of September 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, 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 October 2023, we entered into an agreement with Bristol Myers Squibb (“BMS”), whereby BMS obtained our exclusive rights to develop and commercialize mavacamten in Mainland China, Hong Kong, Macau, Taiwan, Singapore and Thailand, in conjunction with termination of the exclusive license agreement we previously entered into with MyoKardia, Inc., now a wholly owned subsidiary of BMS, in August 2020 to acquire such rights. Under the terms of the agreement, we received a one-time payment of $350 million. In addition, we are released from expected payment obligations of $127.5 million in remaining milestone payments under the MyoKardia license agreement.

In August 2023, we announced that data from the Phase 3 EXPLORER-CN trial of mavacamten in Chinese symptomatic obstructive hypertrophic cardiomyopathy (“oHCM”) patients were presented in a late-breaking science session at the European Society of Cardiology (ESC) Congress 2023 and simultaneously published in JAMA Cardiology, with mavacamten demonstrating statistically significant and clinically meaningful improvement in Valsalva left ventricular outflow tract (LVOT) peak gradient, the study’s primary endpoint.

TP-03

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.

In October 2023, we announced topline data from the Phase 3 LIBRA trial of TP-03 in Chinese patients with Demodex blepharitis. The LIBRA trial met the co-primary endpoint of mite eradication at day 43 (0<0.001). A positive, but not statistically significant trend was observed for the co-primary endpoint of complete collarette cure (p=0.15). TP-03 was well tolerated with a safety profile similar to that observed in other large-scale clinical trials, and there were no treatment-related discontinuations. We plan to discuss these results with the China National Medical Products Administration and expect to use these data to support a New Drug Application filing in China.

Infigratinib

In October 2023, we announced the presentation of efficacy and safety data from a Phase 2a study evaluating infigratinib in Chinese patients with locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 gene amplification at the 2023 European Society for Medical Oncology Congress. Confirmed objective response rate was 23.8% (95% CI: 8.2 – 47.2), disease control rate was 76.2% (95% CI: 52.8 – 91.8) and median duration of response was 3.8 months (95% CI: 3.6 – NE). Median progression-free survival was 3.3 months (95% CI: 2.3 – 4.5) and median overall survival was 8.0 months (95% CI: 4.1 – NE).

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 October 2023, we announced that our Board of Directors initiated a comprehensive strategic review of the Company. The Board of Directors expects to provide an update on its strategic review in the first half of 2024.

In October 2023, the exclusivity period under our exclusivity agreement with BridgeBio Pharma, LLC expired.

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.

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. We maintain regular communication with our vendors and clinical sites to appropriately plan for, and mitigate, the impact of the COVID-19 pandemic on our operations.

Key Components of Results of Operations

Research and development expenses

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

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

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

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

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Research and development expenses (in thousands):				
Licensing fees	—	—	2,500	25,000
Employee related expense	2,873	3,023	8,564	8,609
CRO costs	5,489	4,417	15,768	13,463
Other costs	656	818	2,471	2,106
Total	$ 9,018	$ 8,258	$ 29,303	$ 49,178

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 September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Research and development (income) expenses (in thousands):				
Mavacamten	2,809	2,109	6,491	10,813
Infigratinib	(474)	767	466	3,088
BBP-398	1,898	536	2,785	1,315
NBTXR3	650	721	3,403	2,178
LYR210	10	86	74	5,200
TP-03	768	546	5,933	16,342
Employee related expenses	2,873	3,022	8,564	8,610
Other costs	484	471	1,587	1,632
Total	$ 9,018	$ 8,258	$ 29,303	$ 49,178

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, 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 of $0.6 million and $1.2 million for the three and nine months ended September 30, 2023 and $0.0 million and $0.0 million for the three and nine months ended September 30, 2022, respectively.

Results of Operations

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

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

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022
Operating expenses (in thousands):		
Research and development	$ 9,018	$ 8,258
General and administrative	17,283	16,291
Total operating expenses	26,301	24,549
Loss from operations	(26,301)	(24,549)
Other income:		
Interest income, net	2,707	1,405
Other income, net	141	1,253
Net loss before income taxes	(23,453)	(21,891)
Income taxes	586	6
Net loss	$ (24,039)	$ (21,897)

Research and development expenses

Research and development expenses increased by $0.7 million from $8.3 million for the three months ended September 30, 2022 to $9.0 million for the three months ended September 30, 2023. For the three months ended September 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) $5.5 million attributable to development activities to support our clinical trials. The remaining expense was attributable to professional fees.

For the three months ended September 30, 2022, research and development cost was primarily attributable to (i) $3.0 million in personnel-related expenses, and (ii) $4.4 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 $16.3 million for the three months ended September 30, 2022 to $17.3 million for the three months ended September 30, 2023. The increase was primarily attributable to a $0.9 million increase in personnel-related expenses, including share-based compensation expense, for increased employee headcount.

Interest income

Interest income increased by $1.3 million from $1.4 million for the three months ended September 30, 2022 to $2.7 million for the three months ended September 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 decreased by $1.2 million from $1.3 million for the three months ended September 30, 2022 to $0.1 million for the three months ended September 30, 2023. The decrease is primarily attributable to foreign exchange losses in our foreign entities and a decrease in depositary fees related to our ADSs.

Income taxes

Our income tax expense was $586.0 thousand, resulting in an effective income tax rate of (2.5)%, for the three months ended September 30, 2023. Our income tax expense was $6.0 thousand, resulting in an effective income tax rate of 0.0%, for the three months ended September 30, 2022. The variation in the effective income tax rate was primarily due to taxable income in foreign jurisdictions in 2023.

Comparison of the nine months ended September 30, 2023 and 2022

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Operating expenses (in thousands):		
Research and development	$ 29,303	$ 49,178
General and administrative	48,011	46,930
Total operating expenses	77,314	96,108
Loss from operations	(77,314)	(96,108)
Other income:		
Interest income, net	7,867	2,238
Other income, net	966	1,873
Net loss before income taxes	(68,481)	(91,997)
Income taxes	1,224	17
Net loss	$ (69,705)	$ (92,014)

Research and development expenses

Research and development expenses decreased by $19.9 million from $49.2 million for the nine months ended September 30, 2022 to $29.3 million for the nine months ended September 30, 2023. For the nine months ended September 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. clinical supply agreement (the "Tarsus Supply Agreement"), (ii) $8.6 million in personnel-related expenses, including share-based compensation expense, and (iii) $15.7 million attributable to development activities to support our clinical trials. The remaining expense was attributable to professional fees.

For the nine months ended September 30, 2022, research and development cost was primarily attributable to (i) $15.0 million related to a development milestone payment payable pursuant 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) $13.5 million attributable to development activities to support our clinical trials and (v) $8.6 million in personnel-related expenses, including share-based compensation expense. The remaining expense was attributable to professional fees.

General and administrative expenses

General and administrative expenses increased by $1.1 million from $46.9 million for the nine months ended September 30, 2022 and $48.0 million for the nine months ended September 30, 2023. The increase was primarily attributable to a $3.8 million increase in personnel-related expenses, including share-based compensation expense, for increased employee headcount. This increase was partially offset by a $1.3 million decrease in legal service costs, consulting costs and accounting services. The remaining decrease was attributable to a decrease in insurance and other operating costs.

Interest income

Interest income increased by $5.7 million from $2.2 million for the nine months ended September 30, 2022 to $7.9 million for the nine months ended September 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 decreased by $0.9 million from $1.9 million for the nine months ended September 30, 2022 to $1.0 million for the nine months ended September 30, 2023. The decrease is primarily attributable to foreign exchange losses in our foreign entities and a decrease in depositary fees related to our ADSs.

Income taxes

Our income tax expense was $1.2 million, resulting in an effective income tax rate of (1.8)%, for the nine months ended September 30, 2023. Our income tax expense was $17.0 thousand, resulting in an effective income tax rate of 0.0%, for the nine months ended September 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 September 30, 2023, we had cash and cash equivalents and marketable securities of $252.2 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 expenses. Our use of cash is impacted by the timing and extent of the required payments for each of these activities.

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

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

- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the cost and timing associated with commercializing our product candidates, if they receive regulatory approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following regulatory approval;
- the impact of the COVID-19 pandemic and the Russian invasion of Ukraine on our clinical development or operations; and
- the costs associated with being a public company.

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

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

Cash flows

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Net cash (used in) provided by (in thousands):		
Operating activities	$ (52,814)	$ (68,472)
Investing activities	78,044	(80,197)
Financing activities	—	1,710

Net cash used in operating activities

During the nine months ended September 30, 2023, operating activities used approximately $52.8 million of cash, primarily due to our net loss of $69.7 million, and non-cash consideration of $3.4 million and $1.2 million related to the amortization of discounts on investments and unrealized foreign currency transaction gains, respectively, partially offset by non-cash consideration of $13.3 million related to share-based compensation expense, $1.0 million related to depreciation expense and $7.2 million related to changes in operating assets and liabilities.

During the nine months ended September 30, 2022, operating activities used approximately $68.5 million of cash, primarily due to our net loss of $92.0 million, and non-cash consideration of $1.4 million related to unrealized foreign currency transaction gains, partially offset by non-cash consideration of $13.9 million related to share-based compensation expense and $10.4 million related to changes in operating assets and liabilities.

Net cash used in investing activities

During the nine months ended September 30, 2023, investing activities provided approximately $78.0 million, consisting of approximately $206.4 million from the sales and redemption of marketable securities, partially offset by $128.1 million from the purchases of marketable securities.

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

Net cash provided by financing activities

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

During the nine months ended September 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 nine months ended September 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 September 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 September 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, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023.

We cannot assure you that the strategic review initiated by our Board of Directors will result in any transactions or other strategic changes or outcomes; and there may be negative impacts on our business and the price of our ADSs as a result of this strategic review.

In October 2023, we announced that our Board of Directors has initiated a comprehensive strategic review of the Company. The Board of Directors expects to provide an update on the strategic review in the first half of 2024. There can be no assurance that the strategic review process will result in any transactions or any other strategic changes or outcomes, or as to the timing of any of the foregoing. Whether the process will result in any transactions, and our ability to complete any such transactions, will depend on numerous factors, some of which are beyond our control, including the interest of potential acquirers or strategic partners in a potential transaction, the value potential acquirers or strategic partners attribute to our business, market conditions, interest rates and industry trends. The price of our ADSs may be adversely affected if the strategic review does not result in any transactions or any other strategic changes or outcomes, or if one or more transactions are consummated on terms that investors view as unfavorable to us. Even if one or more transactions are completed, there can be no assurance that any such transactions will be successful or have a positive effect on the value of our ADSs. In addition, our financial results and operations could be adversely affected by the strategic review process and by the uncertainty regarding its outcome. The attention of management and our Board of Directors could be diverted from our core business operations, and we may divert capital and other resources to the process that otherwise could have been used in our business operations. We could incur substantial expenses associated with identifying and evaluating potential strategic alternatives, including those related to equity compensation, severance pay and legal, accounting and financial advisor fees.

In addition, the process could lead us to lose or fail to attract, retain and motivate key employees or to lose or fail to attract business partners. Furthermore, in the past, securities litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential transaction or the ultimate value to of a transaction.to our shareholders and holders of our ADSs.

In addition, speculation regarding any developments related to the strategic review and perceived uncertainties related to the future of the Company could cause the price of our ADSs to fluctuate significantly.

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 that our transfers of data out of Mainland China currently or in the past require us to undergo a mandatory security assessment under the Security Assessment Measures, but we may in the foreseeable future conduct cross-border data transfers of data that require us to undergo a mandatory security assessment under the Security Assessment Measures for such transfers.

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 came into effect on June 1, 2023. After this came 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, Use of Proceeds and Issuer Purchases of Equity Securities.

(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.

Not applicable.

Item 6. Exhibits.

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

Exhibit No.	Description
10.1#	Supplemental Agreement for nHCM, dated as of August 11, 2023, by and between MyoKardia, Inc., LianBio, LianBio Licensing, LLC, Lian Cardiovascular Limited, and Shanghai LianBio Development Co., Ltd.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Database*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

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

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

LianBio

Date: November 13, 2023

By: /s/ Yizhe Wang

Yizhe Wang

Chief Executive Officer and Director

(Principal Executive Officer)

Date: November 13, 2023

By: /s/ Yi Larson

Yi Larson

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

SUPPLEMENTAL AGREEMENT FOR NHCM

THIS SUPPLEMENTAL AGREEMENT FOR NHCM (this "**nHCM Supplemental Agreement**"), dated as of August 11, 2023 (the "**nHCM Supplemental Agreement Effective Date**"), is made by and between MyoKardia, Inc., a corporation organized and existing under the laws of the State of Delaware, having its place of business at 1000 Sierra Point Parkway, Brisbane, California 94005 United States ("**Company**"), on the one hand, and LianBio, an exempted company organized under the laws of the Cayman Islands ("**LianBio**"), LianBio Licensing, LLC, a limited liability company organized and existing under the laws of the State of Delaware, having its place of business at 103 Carnegie Center Drive Suite 215, Princeton, NJ 08540 ("**LianBio Licensing**"), and Lian Cardiovascular Limited, a private company limited by shares organized under the laws of Hong Kong ("**Lian Cardiovascular HK**"), and Shanghai LianBio Development Co., Ltd., a limited liability company organized and existing under the laws of the PRC ("**Local Regulatory Agent**", and collectively with LianBio, LianBio Licensing and Lian Cardiovascular HK, "**Licensee**," and each, individually, a "**Licensee Party**"), on the other hand. Company and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Company, LianBio and LianBio Licensing are parties to that certain Exclusive License Agreement dated as of August 10, 2020, as amended October 8, 2020 and January 4, 2021 (the "**License Agreement**") pursuant to which Company granted to Licensee certain rights and licenses under intellectual property owned or controlled by Company to Develop, have Manufactured and Commercialize the Compound and Licensed Products in the Field in the Territory (each, as defined in the License Agreement);

WHEREAS, [***]

WHEREAS, LianBio Licensing assigned its rights and obligations under the License Agreement to Lian CV under the Contribution, Assignment and Assumption Agreement dated as of September 28, 2021, and Lian CV assigned its rights and obligations under the License Agreement to Lian Cardiovascular HK under the Contribution, Assignment and Assumption Agreement dated as of September 28, 2021;

WHEREAS, Company wishes to allow Licensee to conduct, and Licensee wishes to conduct, a portion of the Global Clinical Study (as defined below) in the PRC (as defined in the License Agreement); and

WHEREAS, the Parties wish to enter into a supplemental agreement to provide for additional terms and conditions that govern each Party's rights and responsibilities with respect to activities to be conducted in the PRC with respect to such portion of the Global Clinical Study.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

Article I
DEFINITIONS

As used herein, the following terms shall have the following meanings. Capitalized terms used herein but not otherwise defined shall have the meanings ascribed to them in the License Agreement.

Section 1.1 "**Acquirer**" means, with respect to a Change of Control of a Licensee Party, the applicable third party as referred to in the definition of "Change of Control" under the License Agreement and under this nHCM Supplemental Agreement.

Section 1.2 "[***]" has the meaning set forth in Section 2.4(c).

Section 1.3 "[***]" has the meaning set forth in Section 2.4(c).

Section 1.4 "**Adverse Event**" or "**AE**" means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product, including those required to be reported under applicable Laws in the PRC. An AE does not necessarily have a causal relationship with a product, that is, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

Section 1.5 "**Allocable Global Study Costs**" has the meaning set forth in Section 2.4(b).

Section 1.6 "**Ancillary Agreement**" means each of the Development Supply Agreement, the Clinical Quality Agreement and the PV Agreement.

Section 1.7 "**Anti-Corruption Laws**" has the meaning set forth in Section 5.4(a).

Section 1.8 "**Breaching Party**" has the meaning set forth in Section 9.2.

Section 1.9 "**Change of Control**" has the meaning ascribed to such term in the License Agreement; *provided* that, with respect to a Licensee Party, a "Change of Control" shall also include the sale, transfer, exclusive license or other disposition to a third party that is not an Affiliate of such Licensee Party, in a transaction or a series of related transactions, of all or substantially all of such Licensee Party's and its controlled Affiliates' assets related to the Compound.

Section 1.10 "**China Study**" means, with respect to the Global Clinical Study, the portion of such Global Clinical Study to be conducted in the PRC.

Section 1.11 "**China Study Development Plan**" has the meaning set forth in Section 2.2(a).

Section 1.12 "**China Study Key Milestones**" mean [***].

Section 1.13 "[***]" has the meaning set forth in Section 2.2(b).

Section 1.14 "[***]" has the meaning set forth in Section 2.2(b).

Section 1.15 "**China Study Regulatory Filings**" means any documentation comprising any filing or application with, and any documents submitted to, any Regulatory Authority in the PRC with respect to the China Study, including CTA(s), ethics committee approval(s), HGR Approval(s) and all correspondence with any Regulatory Authority with respect to the China Study (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority with respect to the China Study). For clarity, China Study Regulatory Filings shall exclude Regulatory Approval Applications, Regulatory Approvals, and Marketing Authorizations.

Section 1.16 "**Clinical Quality Agreement**" means that certain Quality Agreement between Company, on the one hand, and Lian Cardiovascular HK and Local Regulatory Agent, on the other hand, effective as of August 13, 2021, as may be amended from time to time.

Section 1.17 "**Company**" has the meaning set forth in the preamble hereto.

Section 1.18 "**Company Territory**" means (a) the world other than the Territory, and (b) any and all Region(s) with respect to which the License Agreement is terminated pursuant to the terms thereof.

Section 1.19 "**Company Trainers**" has the meaning set forth in Section 5.3.

Section 1.20 [***]

Section 1.21 "**Compliance Failure**" has the meaning set forth in Section 9.2.

Section 1.22 "**Compliance Program**" has the meaning set forth in Section 5.1(b).

Section 1.23 "**Compliance Program Confirmation**" has the meaning set forth in Section 5.1(b).

Section 1.24 "**Compliance Standards**" has the meaning set forth in Section 5.1(b).

Section 1.25 "**Confidentiality Exceptions**" has the meaning set forth in Section 2.2(a).

Section 1.26 "**Connected Dispute**" has the meaning set forth in Section 10.2(c).

Section 1.27 "**CRO**" means a Third Party contract research organization.

Section 1.28 "**CTA**" means a Clinical Trial Application filed with the NMPA for authorization to commence clinical studies in the PRC and all supplements and amendments (including annual reports) that may be filed with respect to the foregoing. With respect to the China Study, the terms "IND" and "CTA" are used interchangeably to mean a Clinical Trial Application filed with the NMPA for authorization to commence the China Study and all supplements and amendments (including annual reports) that may be filed with respect to the foregoing.

Section 1.29 "**Curable Compliance Failure**" has the meaning set forth in Section 9.2.

Section 1.30 "**Data Governance System**" has the meaning set forth in Section 2.9.

Section 1.31 "**Development Supply Agreement**" means that certain Development Supply Agreement among LianBio, LianBio Licensing, Lian Cardiovascular HK, Local Regulatory Agent, on the one hand, and Company, on the other hand, effective as of August 12, 2021, as may be amended from time to time.

Section 1.32 "**Diligent Efforts**" means, with respect to any task or activity, applying the necessary resources and personnel to complete such task or activity in a timely manner, including (a) assigning responsibility for such task or activity to specific employee(s) with appropriate experience and expertise and monitoring such progress; (b) setting and seeking to achieve specific and meaningful objectives for carrying out such task or activity; and (c) making and implementing decisions and allocating resources designed to advance progress with respect to such task or activity. For clarity, the foregoing standard is not intended to guarantee a particular result with respect to a task or activity.

Section 1.33 "**Enrollment Completion Date**" has the meaning set forth in Section 2.2(b).

Section 1.34 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et. seq., as it may be amended, and the rules, regulations, guidance, guidelines, and requirements promulgated or issued thereunder.

Section 1.35 "**GCP**" or "**Good Clinical Practice**" means all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Studies, including, as applicable, (a) as set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) as set forth in the PRC Good Clinical Practice for Pharmaceuticals, as released by the NMPA in 2020, and its subsequent amendments and related rules and guidelines, including the Drug Good Pharmacovigilance Practice Rule effective as of December 1, 2021, (d) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (e) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

Section 1.36 "**Global Clinical Study**" means the multi-regional Clinical Study with respect to a Licensed Product that is intended to support regulatory approval of such Licensed Product both within and outside of the Territory for nHCM and is conducted in multiple countries, regions, territories and medical institutions.

Section 1.37 "[***]" has the meaning set forth in Section 2.2(b).

Section 1.38 "**Global Study Data and Filings**" has the meaning set forth in Section 2.8.

Section 1.39 "**GLP**" or "**Good Laboratory Practice**" means all applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, the PRC Good Laboratory

Practice effective as of September 1, 2017, or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (OECD), and such standards of good laboratory practice as are required by the equivalent applicable Laws in the relevant Region and other organizations and governmental agencies in countries in which the Licensed Product is intended to be sold by the Party that is subject to such standards.

Section 1.40 "**HGR Approval**" means all filings to, or approvals, certificates or other clearances from the OHGRA that are necessary for commencing research in the form of an international collaboration and disclosing to, transferring to or sharing with a "foreign party" any "Chinese human genetic resource information" or "Chinese human genetic resource materials", each of the foregoing terms as defined in the PRC Regulation on the Administration of Human Genetic Resources ( ). For the avoidance of doubt, HGR Approval includes any amendments to approvals for international collaborations granted by OHGRA and record filings with OHGRA for data transfer.

Section 1.41 [***]

Section 1.42 "**Investigator**" means an investigator who participates in the China Study.

Section 1.43 "**JDC**" has the meaning set forth in Section 4.2.

Section 1.44 "**Joint Compliance Committee**" has the meaning set forth in Section 4.3.

Section 1.45 "**Law**" or "**Laws**" means all laws, statutes, rules, codes, regulations, standards, orders, decrees, judgments or ordinances of any Governmental Authority, or any license, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

Section 1.46 "**Lian Cardiovascular HK**" has the meaning set forth in the preamble hereto.

Section 1.47 "**Lian CV**" has the meaning set forth in the recitals.

Section 1.48 "**LianBio Licensing**" has the meaning set forth in the preamble hereto.

Section 1.49 "**License Agreement**" has the meaning set forth in the recitals.

Section 1.50 "**Licensee**" has the meaning set forth in the preamble hereto.

Section 1.51 "**Licensee China Study Development Activities**" has the meaning set forth in Section 2.2(a).

Section 1.52 "[***]" has the meaning set forth in Section 2.2(c).

Section 1.53 "**Licensee Party**" has the meaning set forth in the preamble hereto.

Section 1.54 "[***]" has the meaning set forth in Section 2.2(c).

Section 1.55 "**Licensee Trainers**" has the meaning set forth in Section 5.3.

Section 1.56 "**Local Regulatory Agent**" has the meaning set forth in the preamble hereto.

Section 1.57 "**Mava Agreements**" means each of (a) the License Agreement, (b) this nHCM Supplemental Agreement, (c) [***], and (d) any Ancillary Agreement.

Section 1.58 "**nHCM Supplemental Agreement**" has the meaning set forth in the preamble hereto.

Section 1.59 "**nHCM Supplemental Agreement Effective Date**" has the meaning set forth in the preamble hereto.

Section 1.60 "**NMPA**" means the National Medical Product Administrations of the PRC, or its successor, including any functional subdivisions or centers thereof (e.g., Center for Drug Evaluation).

Section 1.61 "**Non-Breaching Party**" has the meaning set forth in Section 9.2.

Section 1.62 [***]

Section 1.63 "**OHGRA**" means the Office of Human Genetic Resource Administration within the Ministry of Science and Technology in the PRC.

Section 1.64 "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

Section 1.65 "**Patient-Level Study Payments**" means [***].

Section 1.66 [***]

Section 1.67 "**Permitted Subcontractor**" has the meaning set forth in Section 2.3.

Section 1.68 [***]

Section 1.69 [***]

Section 1.70 "**Publication**" means any abstract, manuscript or presentation (including, for clarity, any oral or poster presentation).

Section 1.71 "**PV Agreement**" means that certain Pharmacovigilance Agreement between Bristol Myers Squibb Company and Lian Cardiovascular HK regarding Mavacamten (MYK-461) in the Territory, effective as of June 4, 2021, as may be amended from time to time.

Section 1.72 "**Regulatory Meeting**" has the meaning set forth in Section 3.2(a).

Section 1.73 "**Representatives**" means, with respect to Licensee, its Affiliates, Permitted Subcontractors and Study Sites, and its and their respective officers, directors, employees (including, with respect to Study Sites, Investigators), agents, representatives and other personnel.

Section 1.74 [***].

Section 1.75 "**Senior Officers**" means (a) with respect to Company, the [***], or his/her delegates and (b) with respect to Licensee, the Chief Executive Officer. If the position of any of the Senior Officers identified in this definition no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable title of the Senior Officer set forth herein will be replaced with the title of another executive officer with responsibilities and seniority comparable to the eliminated Senior Officer, and the relevant Party will promptly provide notice of such replacement title to the other Party.

Section 1.76 "**SMO**" means a Third Party site management organization.

Section 1.77 "**Sponsor**" means, with respect to a Clinical Study, the Person who applies for and holds in its name the IND or CTA for such Clinical Study.

Section 1.78 "**Study Data**" means, collectively, all data and information collected, received or otherwise generated in connection with the China Study, including all raw data collected or analyzed and all study reports and documents summarizing or analyzing such data.

Section 1.79 "**Study Guidelines**" mean the guidelines for the China Study, including: (a) the design of the China Study; (b) the full protocol for the China Study (and, to the extent required by applicable Laws, a PRC-specific protocol for the China Study developed by the Parties and approved by Company in writing at its sole discretion); (c) plans with respect to data collection, storage, transfer, cleaning, review, and analysis; (d) scientific integrity and statistical analysis plans, data review plans, informed consent forms, and any investigator's brochure(s); (e) plans with respect to the study subject safety and appropriate compensation in the event of an injury arising from the China Study; and (f) the selection process and criteria for Study Sites, subcontractors (including CROs and SMOs) and recruitment of consultants, in each case ((a) through (f)), provided to Licensee by Company, as may be amended from time to time. For clarity, Study Guidelines constitutes an integral part of, and are hereby incorporated into this nHCM Supplemental Agreement.

Section 1.80 "**Study Site**" has the meaning set forth in Section 2.2(e).

Section 1.81 "**Term**" has the meaning set forth in Section 9.1.

Article II
COMPANY-SPONSORED STUDIES

Section 1.1 **Overview**.

(a) The Parties acknowledge that, as of the nHCM Supplemental Agreement Effective Date, Company is the Sponsor for the Global Clinical Study.

(b) For the China Study, Company will be the Sponsor of the China Study and will appoint the Local Regulatory Agent as Company's regulatory agent in the PRC to prepare, submit and maintain any China Study Regulatory Filing to a Regulatory Authority in the PRC in connection with the China Study, and to conduct other development or regulatory activities to be performed by the Local Regulatory Agent with respect to the China Study as provided herein, in each case, subject to Company's oversight provided herein.

(c) Prior to or together with submitting the CTA for the China Study, the Local Regulatory Agent shall submit to the applicable Regulatory Authority a delegation of authority form approved and signed by Company (or its applicable Affiliate) delegating to the Local Regulatory Agent specified activities to be conducted by the Local Regulatory Agent in connection with the China Study. For clarity, the Local Regulatory Agent shall perform all applicable activities under this nHCM Supplemental Agreement and the License Agreement applicable to the Local Regulatory Agent with respect to the China Study; *provided* that [***].

(d) The terms and conditions of this nHCM Supplemental Agreement shall apply solely with respect to the China Study. The License Agreement, together with this nHCM Supplemental Agreement, shall, with effect on and from the nHCM Supplemental Agreement Effective Date, be read and construed as one document and (a) references in the License Agreement to "this Agreement" and (b) references in any Ancillary Agreement to the License Agreement shall, in each case ((a) and (b)), incorporate references to this nHCM Supplemental Agreement during the Term and thereafter with respect to any surviving provisions. In the event of a conflict between the terms of this nHCM Supplemental Agreement and the terms of the License Agreement with respect to the Global Clinical Study, the terms of this nHCM Supplemental Agreement shall govern with respect to the Global Clinical Study, including the China Study. [***] In the event of any conflict between this nHCM Supplemental Agreement and the Exhibits hereto, this nHCM Supplemental Agreement shall prevail. In the event of any conflict between this nHCM Supplemental Agreement and any Ancillary Agreement, this nHCM Supplemental Agreement shall prevail.

Section 1.2 **Conduct of the China Study**.

(a) Licensee shall carry out the China Study in accordance with a written development plan for the China Study (as amended from time to time in accordance with this Section 2.2(a) and Section 4.6), which development plan shall be reviewed and approved by the JSC promptly (and in any event within [***]) following the nHCM Supplemental Agreement Effective Date and shall be incorporated into this nHCM Supplemental Agreement by reference (the "**China Study Development Plan**"), and in accordance with the Study Guidelines, under the oversight and subject to the authority of the JSC, subject to the final decision-making authority of Company as provided hereunder. The China Study Development Plan shall include the descriptions and timelines (including the Enrollment Completion Date) of the China Study activities assigned to Licensee (the "**Licensee China Study Development Activities**"), including the number of patients to be enrolled in the PRC by Licensee for the China Study. As between the Parties, Company shall have the sole right to prepare and provide to Licensee any Study Guidelines; *provided* that with respect to any PRC-specific protocol for the China Study as may be required by applicable Laws in the PRC, [***]. From time to time, Company may amend the Study Guidelines and the China Study Development Plan by proposing an amendment (including an amendment as required by the applicable Regulatory Authority) to the JSC for review and approval, which amendment shall become effective upon approval by the JSC; *provided* that if the JSC cannot reach consensus on the proposed amendment at a duly called meeting of the JSC, Company shall have final decision-making authority with respect to any such proposed amendment. For clarity, to the extent any activities with respect to the Global Clinical Study planned by Company to be conducted by or on behalf of Company or for any Region, country or jurisdiction outside the PRC is included in the China Study Development Plan, such activities shall be for informational purposes only, shall be non-binding, and, subject to clauses (i) through (iv) in the definition of Confidential Information in the License Agreement ("**Confidentiality Exceptions**"), shall be deemed to be Company's Confidential Information.

(b) The Parties acknowledge and agree that, as of the nHCM Supplemental Agreement Effective Date, their intent is that [***]. Any amendment (to the extent permitted by applicable Laws) to the [***] or the [***] shall be reviewed and approved by the JSC, subject to the final decision-making authority of Company as provided in Section 4.6. Licensee shall use Commercially Reasonable Efforts to achieve the China Study Key Milestones; *provided* that if [***] then, [***]. In the event Licensee fails to achieve the China Study Key Milestone set forth in clause (a) of Section 1.12, (A) for clarity, Licensee shall continue to carry out the China Study in accordance with this Agreement (including, for clarity, the China Study Development Plan), (B) Company shall have the right to continue the conduct of the Global Clinical Study outside of the PRC in its sole discretion, including to close patient enrollment, and to start data read-out, for the Global Clinical Study, (C) without limitation to the foregoing clause (B) and notwithstanding anything to the contrary herein, in no event shall Company be required to delay any timeline, deadline or commencement of any activity conducted in connection with the Global Clinical Study, (D) the Parties shall discuss in good faith the regulatory strategy with respect to applying for and obtaining Regulatory Approval of the Licensed Product for nHCM in the PRC, and (E) without limitation to the foregoing clauses (B) and (C), Company will have the final decision-making authority, without further resort to any other dispute resolution mechanism, on all matters that relate to the China Study. In the event of a change to the [***] or the [***], the Parties shall discuss in good faith possible revision(s) to [***] and the Parties may agree (but will not be obligated to agree) through the JSC or in writing to [***], subject to Company's final decision-making authority. Notwithstanding the foregoing or anything else herein, (1) [***] will [***] once the [***] is reached, subject to Company's final decision-making authority in Section 4.6(c) (including, for clarity, Company's final decision-making authority with respect to any amendment to the [***] or [***]) and (2) [***].

(c) The Parties acknowledge that, [***] to the extent permitted by applicable Laws and subject to this Section 2.2(c), Licensee shall be permitted to [***]; *provided* that, Licensee shall not, and shall cause its Affiliates not to, [***] unless and until the Parties have discussed and [***]. Notwithstanding the foregoing or anything else herein, [***], Licensee shall be permitted to [***], and Licensee shall provide Company with an opportunity to [***]. Subject to the foregoing, Company will provide such requisite materials or documents as mutually agreed by the Parties to be provided by Company [***]. After the foregoing [***] and prior to [***], Licensee shall not, and shall cause its Affiliates not to, directly or indirectly through any Third Party, conduct any activities [***], (iii) conducting any other activities relating to or in furtherance of [***], or (iv) [***]. Prior to [***], the Parties shall discuss in good faith the regulatory strategy with respect to [***], including whether Licensee (or its designated Affiliate) shall be permitted to [***]. At any time following [***] Licensee shall have the right to [***], *provided* that (1) for clarity, Licensee shall [***] in accordance with a JSC-approved [***] for the Licensed Product in the PRC for nHCM as set forth in the License Agreement (including Section [***] of the License Agreement), which [***], once approved by the JSC, shall be [***], (2) Licensee shall [***] in compliance with [***], and the terms and conditions set forth in Section 2.2(d), Section 5.1(b) (the last sentence only), Section 5.2, Section 5.3, and Section 5.4 [***], and (3) in the event Licensee's conduct [***], Company may provide written notice to Licensee of such breach and require Licensee to [***] until such time as such breach is remedied (if such breach is capable of being remedied) [***], and Licensee will [***] as permitted by and in accordance with Applicable Laws. For the avoidance of doubt, in no event shall Company be required to [***].

(d) Licensee shall, and shall cause its applicable Affiliates, Permitted Subcontractors, Study Sites and Investigators to conduct the China Study [***] and perform

other applicable activities with respect thereto in accordance with applicable Laws (including applicable GLP and GCP), the terms and conditions of this nHCM Supplemental Agreement and the License Agreement, and the Study Guidelines.

(e) The Local Regulatory Agent shall enter into a clinical trial agreement with each clinical site that will conduct the China Study (each, a "**Study Site**"), in each case substantially in the form of **Exhibit 2.2(e)** attached hereto; *provided* that Licensee shall obtain Company's written consent to each such Study Site prior to entering into such agreement. Company shall provide its approval or disapproval [***] of a Study Site proposed by Licensee within [***] of [***], which notice shall be accompanied by sufficient information for Company to assess the qualifications of such proposed Study Site as set forth in Section 2.3 and all information for such proposed Study Site and applicable Investigator(s) as requested by Company pursuant to Section 2.2(f). Without limitation to the foregoing, Licensee shall not enter into any clinical trial agreement with a Study Site that contains any material deviation from **Exhibit 2.2(e)** without the prior written approval from Company. Company shall provide its approval or disapproval of a clinical trial agreement containing any such material deviation within [***] of its receipt of a copy of such clinical trial agreement provided by Licensee. For the purpose of this Section 2.2(e), any change to the provisions with respect to [***] in **Exhibit 2.2(e)** or the addition of any new term or requirement to **Exhibit 2.2(e)** shall be deemed to be a material deviation. Licensee shall cause each Study Site to comply strictly with, and not to deviate from, the Study Guidelines in the conduct of the China Study, and shall promptly notify Company in writing of any deviation from the Study Guidelines by any Study Site. Without limitation to the foregoing, Licensee shall cooperate with Company in the enforcement of any such clinical trial agreement at Company's direction and shall terminate, or cause to be terminated, any such clinical trial agreement upon Company's request. The Parties acknowledge that Licensee may lead the negotiation of a clinical trial agreement with a Study Site to the extent such clinical trial agreement does not contain any material deviation from **Exhibit 2.2(e)**. Notwithstanding the foregoing, Company reserves the right to lead or participate in the negotiation of a clinical trial agreement with any Study Site and/or to be a party to the clinical trial agreement with any Study Site as Company deems necessary or appropriate. For clarity, neither the attachment of the form clinical trial agreement in **Exhibit 2.2(e)** hereto, nor Company's approval of or being a party to any clinical trial agreement with a Study Site or Company's approval of any subcontract agreement between Licensee and the applicable Permitted Subcontractor, is intended, or shall be construed, to relieve Licensee of any of its obligations under this Agreement or any Ancillary Agreement (including any such obligations with respect to any Permitted Subcontractor, Study Site or Investigator).

(f) Upon Company's request, Licensee shall promptly provide the following to Company for each Study Site and Investigator: (i) any documentation required under applicable Law to demonstrate the Investigator's suitability to participate in the China Study and such Investigator's curriculum vitae, each signed by such Investigator, or any other similar documentation or information as Company may reasonably request, (ii) any documents required under applicable Law relating to the financial interests of such Study Site and the applicable Investigator and any sub-investigators in the China Study, including financial disclosure statements in FDA form 1572 or any applicable foreign equivalent thereof, (iii) documentation showing that the applicable ethics committee has reviewed and approved the applicable protocol, the applicable informed consent forms and any other information to be provided to potential subjects of the China Study to secure their informed consent, which informed consent forms and other information have been provided or approved by Company and comply with applicable Law, (iv) documentation showing that the applicable ethics committee has reviewed and

approved any materials with respect to the conduct of the China Study, including any materials with respect to safety reporting, (v) the fully executed clinical trial agreement with such Study Site, and (vi) such other statements, information or documents as Company may reasonably require pursuant to applicable Law.

(g) Unless otherwise instructed by Company, (i) Licensee shall be responsible for all communications with the Study Sites and Investigators with respect to the China Study in accordance with the China Study Development Plan and, to the extent not specifically set forth in the China Study Development Plan, as directed by Company, and (ii) prior to the commencement of any portion of the China Study at a Study Site, Licensee shall provide each applicable Investigator with the protocol and such other materials required to conduct the China Study, as directed by Company. Except as otherwise agreed by Company in writing, no changes, whether [***] or otherwise, shall be made to the protocol or any other Study Guidelines provided by Company with respect to the China Study. Licensee shall (A) keep Company reasonably informed by providing Company with a reasonably detailed written summary in English of any material communication with a Study Site or Investigator within [***] following such communication, and a reasonably detailed written summary in English of all non-material communications with all Study Sites and all Investigators on a [***] basis, except to the extent provided in the following clause (D), (B) provide Company notice of any scheduled meetings (including telephone conferences) with a Study Site or Investigator at least [***] prior thereto, (C) use best efforts to provide Company notice of any unscheduled meeting (including telephone conference) with a Study Site or Investigator as soon as practicable, and (D) provide Company with a reasonably detailed written summary in English of (1) any unscheduled meeting (including telephone conference) with any Study Site or Investigator and (2) any scheduled meeting (including telephone conference) with any Study Site or Investigator that Company elects not to participate in, in each case (1) and (2), promptly (and in any event within [***]) thereafter. Company shall have the right, at its sole discretion and at any time, to lead or participate in any meeting, telephone conference, discussion or other communication with any Study Sites or Investigators [***].

(h) Licensee shall promptly (and, if requested by Company, within [***] after Company's request) furnish to Company any information or materials necessary or useful for Company to comply with its legal obligations as the Sponsor of the China Study under applicable Laws. In addition, Licensee shall assist Company to comply with its legal obligations as the Sponsor for the China Study, including obtaining and maintaining all applicable approvals from NMPA for the China Study (including applicable ethics committee approval, HGR Approval, and approval of the CTA).

(i) Each Party shall as soon as practicable (and in any event within [***]) notify the other Party of any event, notification or information that such Party becomes aware of that could reasonably be expected to: (i) result in legal or regulatory action against the Sponsor or Local Regulatory Agent for the China Study or (ii) affect the quality or the integrity of the China Study. If either Party learns of any enforcement action by the Regulatory Authorities in the PRC against Company (or its applicable Affiliates), Licensee (or its applicable Affiliates) or any Permitted Subcontractor, Study Site or Investigator, such Party shall as soon as practicable (and in any event within [***]) notify the other Party thereof. With respect to any such action that is related to the China Study, Licensee shall (A) in the event of any such action against Company or its applicable Affiliates, provide all assistance as Company may reasonably request to resolve or, to the extent not resolvable, alleviate such action, and (B) in the event of any such

action against Licensee or its applicable Affiliates, use Diligent Efforts to resolve [***] such action in consultation with Company.

(j) Notwithstanding anything to the contrary in this nHCM Supplemental Agreement, the License Agreement or any Ancillary Agreement, Licensee shall, and, as applicable, shall cause its Affiliates, Permitted Subcontractors, Study Sites and Investigators to, (i) promptly terminate or suspend the China Study upon written notice from Company of Company's determination (in its sole discretion) that such termination or suspension is warranted because of [***], or (ii) terminate or suspend any portion of the China Study conducted at any Study Site upon written notice from Company and in accordance with Company's instructions including with respect to timing of such termination or suspension; *provided* that, in the case of this clause (ii), [***] such proposed termination or suspension shall be finally determined by Company.

Section 1.3 **Subcontracting**. Except with respect to Study Sites, which are addressed in Section 2.2(e) through Section 2.2(g), Licensee shall not subcontract or delegate any of its obligations under this nHCM Supplemental Agreement to an Affiliate or a Third Party (including any CRO or SMO) without Company's prior written consent (each such approved subcontractor, "**Permitted Subcontractor**"). Licensee certifies that each potential Permitted Subcontractor or Study Site proposed by Licensee for Company's consent has never been, and as of the time of such proposal is not, debarred, excluded, convicted or otherwise ineligible as set forth in clauses (a) through (d) of Section 9.4 of the License Agreement or the last sentence of Section 7.2, and shall provide to Company sufficient information for Company to assess the qualifications of any proposed Permitted Subcontractor or Study Site. Without limitation to the remainder of this Section 2.3, Licensee shall [***]. Any subcontract agreement between Licensee or its applicable Affiliate and a Permitted Subcontractor relating to activities conducted under this nHCM Supplemental Agreement shall require Company's prior written approval. Without limitation to the foregoing, each subcontract agreement shall include provisions requiring the applicable Permitted Subcontractor to comply with all the applicable terms and conditions of this nHCM Supplemental Agreement, the License Agreement and any Ancillary Agreements. Licensee shall be responsible and liable for the compliance of any Permitted Subcontractor or Study Site with the applicable terms and conditions of this nHCM Supplemental Agreement, the License Agreement and any Ancillary Agreements. Any act or omission of such Permitted Subcontractor or Study Site that would be a breach of this nHCM Supplemental Agreement, the License Agreement or any Ancillary Agreements if performed by Licensee will be deemed to be a breach by Licensee under this nHCM Supplemental Agreement, the License Agreement or any Ancillary Agreements, as the case may be. Licensee hereby waives any requirement that Company exhaust any right, power or remedy, or proceed against any Permitted Subcontractor or Study Site, for any obligation or performance under this nHCM Supplemental Agreement, the License Agreement or any Ancillary Agreements prior to proceeding directly against Licensee. A list of Permitted Subcontractors as of the nHCM Supplemental Agreement Effective Date is set forth in **Exhibit 2.3**, which list shall be updated promptly upon Company's written consent to any new Permitted Subcontractor.

Section 1.4 **Costs and Expenses**.

(a) Licensee shall be responsible for all Patient-Level Study Payments and other internal and external costs and expenses incurred by or on behalf of Licensee or its Affiliates to carry out activities in connection with the China Study under this nHCM Supplemental Agreement.

(b) Except to the extent provided otherwise in the third sentence of Section 2.2(b), Licensee will reimburse Company for all internal and external costs and expenses reasonably incurred by or on behalf of Company or its applicable Affiliates for the Global Clinical Study that are generally applicable to both the China Study and the portion of the Global Clinical Study conducted outside of the PRC, to the extent such costs and expenses are reasonably allocable to the China Study based on the actual number of patients that are enrolled in the PRC for the China Study by Licensee (such costs and expenses reasonably allocable to the China Study, the "**Allocable Global Study Costs**"). The Parties acknowledge and agree that the Allocable Global Study Costs for each patient enrolled in the China Study shall be [***]. Company will provide to Licensee an invoice, together with reasonable documentation of the incurrence or accrual of the costs and expenses to be reimbursed, for amounts to be reimbursed to Company under this nHCM Supplemental Agreement on a [***] basis and Licensee will pay such amounts within [***] after receipt of such invoice. Such payments shall be subject to the payment terms of the License Agreement, including Section 6.8 through Section 6.10 and Section 14.2 thereof. The Licensee shall have no right to offset, set off or deduct any amounts paid or reimbursed to Company pursuant to this nHCM Supplemental Agreement from or against the amounts due to Company under the License Agreement. Without limitation to the foregoing, (A) in the event that Company or any of its Affiliates incur any internal or external costs or expenses at the written request of Licensee or any of its Affiliates, and (B) with respect to any amounts owed to Company hereunder, in each case ((A) and (B)), Company will invoice Licensee for such amounts, and Licensee will pay the invoiced amounts within [***] after the date of any such invoice.

(c) In the event the [***] is increased to more than [***] and the [***] is increased to more than [***], and solely to the extent such increase to the [***] directly results from [***] pursuant to [***], [***] shall be responsible for (i) [***], and (ii) [***] incurred by or on behalf of Licensee or its Affiliates to carry out activities in connection with the China Study under this nHCM Supplemental Agreement, in each case ((i) and (ii)), for the [***] as a result of such increase to the [***] (each such [***] and such [***] in clause (ii), collectively, [***]) and solely to the extent such [***] are reasonable and would not have been incurred by Licensee or its Affiliates but for such increase to the [***]; *provided* that (A) all [***] are documented, verifiable and reasonably allocable to the [***], and (B) with respect to [***] will not be responsible for [***] in excess of [***] for [***].

Section 1.5 **Pharmacovigilance**. As soon as reasonably practicable following the nHCM Supplemental Agreement Effective Date, and in any event no later than the first dosing of the first patient in the China Study, the Parties shall amend the PV Agreement to provide that: (a) Licensee will be responsible for collecting all Adverse Events and safety data relating to the Licensed Product in the PRC or the China Study as required by applicable Laws, (b) Licensee will report to Company all Adverse Events and safety data relating to the Licensed Product in the PRC or the China Study and, subject to Section 3.1, will be responsible for reporting (and if instructed by Company, will report) Adverse Events and safety data relating to the Licensed Product or the China Study to applicable Regulatory Authorities in the PRC, as well as responding (and if instructed by Company, will respond) to safety issues and to all requests of Regulatory Authorities in the PRC relating to the Licensed Product or the China Study, in each case within appropriate timeframes and in an appropriate format to ensure Company's compliance with all applicable Laws and fulfillment of all local and international regulatory reporting obligations, and (c) subject to Section 3.1, Licensee shall immediately forward to Company any such inquiry from a Regulatory Authority in the PRC relating to the Licensed Product or the China Study, and shall send any draft responses to Company to review, comment

and approve (in Company's sole discretion) before responding to the applicable Regulatory Authority in the PRC. For clarity, as between the Parties, Company shall have the final decision-making authority with respect to all safety and pharmacovigilance issues (including safety reports) in connection with the China Study.

Section 1.6 **Clinical Quality Agreement**. As soon as reasonably practicable following the nHCM Supplemental Agreement Effective Date, and in any event no later than the initiation of any activities related to any quantity of the Licensed Product for the conduct of the China Study (excluding, for clarity, selection of Study Sites), the Parties shall amend the Clinical Quality Agreement to provide for each Party's rights and responsibilities with respect to quality matters with respect to the Licensed Product supplied for use in the China Study, including (a) Licensee will be responsible for collecting all quality complaints relating to the Licensed Product in the PRC or the China Study as required by applicable Laws, (b) Licensee will report to Company all quality complaints relating to the Licensed Product in the PRC or the China Study, and, subject to Section 3.1, will be responsible for reporting (and if instructed by Company, will report) quality complaints relating to the Licensed Product or the China Study to applicable Regulatory Authorities in the PRC, as well as responding (and if instructed by Company, will respond) to all requests of Regulatory Authorities in the PRC relating to any quality complaints, (c) subject to Section 3.1, Licensee shall immediately forward to Company any such inquiry from a Regulatory Authority in the PRC relating to any quality complaints, and shall send any draft responses to Company to review, comment and approve (in Company's sole discretion) before responding to the applicable Regulatory Authority in the PRC, and (d) if any recall of Licensed Product in the PRC is required under applicable Laws, including any such recall that Company determines must be conducted or that is ordered by the Regulatory Authority in the PRC with respect to the Licensed Product, Licensee shall, under the instruction of Company and at Licensee's own cost and expense, conduct such recall in accordance with applicable Laws and requirements by any Regulatory Authority in the PRC. For clarity, as between the Parties, Company shall have the final decision-making authority with respect to all quality issues (including recalls) in connection with the China Study.

Section 1.7 **Development Supply Agreement**. As soon as reasonably practicable following the nHCM Supplemental Agreement Effective Date, and in any event no later than [***] prior to the planned first shipment of any quantity of the Licensed Product for the conduct of the China Study, the Parties shall amend the Development Supply Agreement to provide for each Party's rights and responsibilities with respect to Company's supply, and Licensee's, its Affiliates' and Permitted Subcontractors' exclusive purchase from Company, of Licensed Product for the conduct of the China Study.

Section 1.8 **Study Data**. Licensee shall, and shall cause its Affiliates, Permitted Subcontractors, Study Sites and Investigators to, comply with its and their obligations (if any) under applicable Laws to provide any notice to and obtain any approval from any Governmental Authority and perform any other government process with respect to its and their collection and processing of Study Data and further agrees to provide such notices to and obtain such approvals from any Governmental Authority, perform such other government processes and take all such other steps as may be required by applicable Laws or as Company may reasonably request from time to time in order to permit Company and its Affiliates to comply with any such notification, approval or other process obligation applicable to Company or its Affiliates in connection with this nHCM Supplemental Agreement or as otherwise necessary for Company or its Affiliates to export and use such Study Data outside the PRC. Licensee shall promptly (unless a more immediate response is required under another section of this nHCM Supplemental Agreement),

upon Company's request, provide Company with copies (in such electronic form as may be reasonably requested by Company) of the results of all activities under the China Study Development Plan and any and all other Inventions or other results generated by or on behalf of Licensee, its Affiliates, Permitted Subcontractors or Study Sites with respect to the China Study, including any Study Data, and completed informed consent forms; *provided* that Licensee shall provide the foregoing results once available and upon Licensee obtaining all requisite approvals required under applicable Law (including PRC data regulations), and Licensee shall obtain all requisite approvals and make all filings required under applicable Law (including PRC data regulations) to provide the foregoing results generated in connection with the China Study no later than [***]. All key results memoranda, and Study Data captured or processed in Company's Global Clinical Study database and any other Study Data that Company requests to be provided in English shall be promptly provided in English. [***]. As between the Parties, any and all Study Data and other Inventions collected, generated or developed hereunder shall be solely owned by Company. Licensee hereby assigns and shall assign, and shall cause its Affiliates, Permitted Subcontractors, Study Sites and Investigators to assign, to Company (or its designee) all of its and their right, title and interest in any Study Data and other Inventions and Patent Rights related thereto. Without limitation to the foregoing, the provisions set forth in Section 7.1(c) of the License Agreement shall apply, *mutatis mutandis*, with respect to any Study Data and Inventions generated hereunder and any Patent Rights related to any of the foregoing (including any portion thereof). Company and its Affiliates shall have the right to use Study Data for any purpose (including, for clarity, providing Study Data to Third Parties) but subject to the second to last sentence in this Section 2.8). Licensee shall take all such steps as may be required by applicable Laws or as Company may reasonably request to obtain any approval or provide any notification required by a Governmental Authority in the PRC to fully effect the ownership of Study Data, Inventions, Patent Rights and China Study Regulatory Filings as provided in this Section 2.8 and Section 3.1(a). For clarity and without limiting the License Agreement (including Section 2.1 therein), subject to the terms and conditions of this nHCM Supplemental Agreement (including, for clarity, Section 6.2), Company hereby grants Licensee access to, and a right of reference with respect to, (a) the data from the Global Clinical Study, including Study Data, and (b) any regulatory filings and applications with, and documents submitted to, any regulatory authority with respect to the Global Clinical Study, including China Study Regulatory Filings ((a) and (b), collectively, "**Global Study Data and Filings**"), in each case ((a) and (b)), to the extent Controlled by Company that are reasonably necessary for Developing and seeking and securing INDs, CTAs, Regulatory Approvals, Marketing Authorizations and Pricing and Reimbursement Approvals of Licensed Products in the Field in the Territory, to Develop and seek and secure INDs, CTAs, Regulatory Approvals, Marketing Authorizations and Pricing and Reimbursement Approvals for Licensed Products in the Field in the Territory. For clarity, as between the Parties, subject to the access right and right of reference granted by Company to Licensee pursuant to the foregoing sentence, Company solely owns all right, title and interest in and to Global Study Data and Filings.

Section 1.9 **Good Data Practice**. Licensee shall, and shall cause its applicable Affiliates, Permitted Subcontractors and Study Sites to, establish and maintain an effective data governance system that will ensure that any Study Data, irrespective of the format in which it is collected, received or otherwise generated, is recorded, processed, transmitted, retained and used to ensure a complete, consistent and accurate record throughout the lifecycle of such Study Data, including meeting the principals of ALCOA+ to ensure the integrity of such Study Data as required by applicable Laws (the "**Data Governance System**"). Except to the extent otherwise provided in any standard operating procedure(s) provided by Company to Licensee, the Data Governance System shall have a process in place for reviewing Study Data (including metadata,

such as audit trail) as per the frequency set forth in Licensee's standard operating procedures. Licensee shall (a) promptly notify Company in writing of any incident that has, or potentially has, any impact on the integrity (e.g., security, accuracy and availability) of Study Data throughout its lifecycle, (b) timely investigate each such incident and take necessary remedial actions promptly, and (c) keep Company reasonably informed of such investigation, any remedial actions taken and the status thereof.

Article III
REGULATORY MATTERS

Section 1.1 **Regulatory Filings, Communications and Approvals Related to the China Study**.

(a) Company or its applicable Affiliates shall own all right, title and interest in and to, and have the sole and exclusive right to hold in its (or its designee's) name, the CTA for the China Study and all other China Study Regulatory Filings. Without limitation to Section 2.8, Company or its applicable Affiliates shall file and hold in its (or its designee's) name the CTA for the China Study and all other China Study Regulatory Filings. For clarity, as between the Parties, (i) Company shall [***], and (ii) Licensee shall [***].

(b) Prior to the submission of the CTA for the China Study, Licensee shall provide Company a list of required documents for such submission and the related submission procedure(s) to, as applicable, obtain all approvals necessary to conduct the China Study as set forth herein, including ethics committee approval, HGR Approval, and approval of the CTA from NMPA; *provided* that if Company considers such list of required documents as overly broad, Licensee shall use Diligent Efforts to communicate with any applicable Regulatory Authority to narrow the list of required document(s).

(c) Subject to Section 3.1(d), Licensee shall be responsible for preparing, submitting and maintaining any China Study Regulatory Filings on Company's behalf and in Company's name in accordance with this Section 3.1(c).

(i) Except as provided in Section 3.2, Licensee shall consult with Company with respect to any China Study Regulatory Filing and shall provide a draft thereof to Company (including, with respect to draft China Study Regulatory Filings that are not in English, a full English translation thereof) at least [***] (or, with respect to correspondence with respect to the China Study with the applicable Regulatory Authority that does not involve any filing, application or document submission, such shorter period of time as may be mutually agreed by the Parties), or where Regulatory Authority timelines require a shorter review period, such shorter period of time as may be required for Company to comply with any applicable regulatory deadline, prior to the date such China Study Regulatory Filing is required to be made to the applicable Regulatory Authority for Company's review, comment and approval, and Licensee shall implement all comments received from Company in connection therewith. Licensee shall not submit to a Regulatory Authority any China Study Regulatory Filing (or any portion thereof) that has not been approved by Company. Licensee shall provide Company with an as-filed copy of any China Study Regulatory Filing and an English translation thereof (to the extent not already in English) as soon as

practicable (and in any event within [***]) after submission to the relevant Regulatory Authority.

(ii) Except as provided in Section 3.2 and Section 2.2(i), Licensee shall notify Company in writing of all communications from a Regulatory Authority with respect to the China Study or any China Study Regulatory Filings no later than [***] after Licensee's receipt thereof and earlier if needed to permit Company's response to a question or deadline, and shall provide Company with a copy of the original communication, a written record of a phone call or oral communication or other documentation. As soon as practicable (and in any event within [***]) after Licensee's receipt of any such communication, Licensee shall provide Company with an English translation of any written communication or other documentation (to the extent not already in English) and a detailed written summary in English of any oral communication.

(iii) Without limitation to the rights and licenses granted by Company to Licensee under Section 2.1 of the License Agreement, to the extent Company provides to Licensee any Confidential Information of Company specifically for use with respect to any China Study Regulatory Filing, Licensee shall only use such Confidential Information for the purpose of the applicable China Study Regulatory Filing.

(iv) Except as provided in Section 3.2, unless otherwise agreed by the Parties, Licensee shall make and respond to all communications with respect to China Study Regulatory Filings to and from the applicable Regulatory Authorities via written or electronic mail or, only if written or electronic mail is not reasonably practical, online inquiry systems of the applicable Regulatory Authority; *provided* that (A) any written communication via written or electronic mail shall include Company as a carbon copied party and (B) Licensee shall provide to Company a copy of any written communication via online inquiry systems of the applicable Regulatory Authority promptly (and in any event within [***]) and an English translation thereof (to the extent not already in English) as soon as practicable (and in any event within [***]).

(v) Licensee shall [***] ensure that the confidentiality of any proprietary portion of any China Study Regulatory Filing and other Confidential Information of Company is protected when submitted to a Regulatory Authority, via such methods as may be directed by Company, and that it is handled and stored in a secure manner by qualified personnel and according to proper procedures and safeguards, including encryption and password protection to prevent unauthorized disclosure. Without limitation to the foregoing, the Local Regulatory Agent shall not include in any communication via WeChat or other social media platforms any Confidential Information of Company or any of its Affiliates.

(d) Company shall have the right to prepare, submit directly to and conduct directly with any applicable Regulatory Authority one or more China Study Regulatory Filings (including Regulatory Meetings), or any portion thereof, at its sole discretion. Subject to Section 3.2, Licensee shall cooperate with and support Company with respect to any applicable China Study Regulatory Filing and Regulatory Meeting, at Company's reasonable request, including by

coordinating and facilitating any discussions between Company and any applicable Regulatory Authority.

Section 1.2 **Regulatory Meetings and Discussions**.

(a) Licensee shall provide written notice to Company of any meetings, telephone conferences or discussions with Regulatory Authorities in the PRC relating to the China Study or any China Study Regulatory Filing (each, a "**Regulatory Meeting**") sufficiently in advance so as to allow for a reasonable opportunity for the Parties to cooperate on the preparation for such Regulatory Meeting and for Company to provide comments or instructions thereon and, in any event, within [***] (or, if Licensee receives any such notice less than [***] prior to the scheduled Regulatory Meeting, within [***]) of Licensee's receipt from the applicable Regulatory Authority of notice of any Regulatory Meeting, [***]; *provided* that Licensee shall provide to Company a detailed written summary in English of [***] as soon as practical (and in any event within [***] after [***]).

(b) Except to the extent Company instructs Licensee otherwise, Company shall have the right to lead, and Licensee shall have the right to attend and participate, in any Regulatory Meeting; *provided* that (i) upon Company's request, Licensee shall recuse itself from any portion of such Regulatory Meeting that relates to proprietary Know-How with respect to the Manufacturing of the Licensed Product and (ii) without limitation to the rights and licenses granted by Company to Licensee under Section 2.1 of the License Agreement, if Licensee obtains or is exposed to any information, whether written or oral, about Company's business or products unrelated to the Licensed Product, such information shall be deemed to be Company's Confidential Information (subject to Confidentiality Exceptions), which Licensee shall not use or disclose for any purpose. To the extent Licensee has access to or is provided with any copy of such Confidential Information, Licensee shall not retain any copy thereof, shall promptly destroy all copies of such Confidential Information in its possession or control and, upon Company's request, shall confirm such destruction in writing to Company.

(c) Unless otherwise agreed by the Parties, for any Regulatory Meeting in which Licensee is participating or leading on behalf of Company (in each case as instructed by Company), (i) the Parties shall cooperate and, to the extent instructed by Company, prepare written messaging and goals in advance of any such Regulatory Meeting, (ii) Licensee shall implement comments and instructions made by Company and comply with any applicable written messaging and goals in the conduct of such Regulatory Meeting, and (iii) Licensee shall prepare and provide for Company's review and approval draft written minutes (and English translations thereof) promptly (and in any event within [***]) after each such Regulatory Meeting and shall implement any reasonable comments of Company on such draft minutes. With respect to any such Regulatory Meeting that Company elects, in its sole discretion, not to participate in, Licensee shall provide Company with (A) [***] in English of such Regulatory Meeting within [***] after such Regulatory Meeting and (B) [***] in English of such Regulatory Meeting within [***] after such Regulatory Meeting. For clarity, any submission of China Study Regulatory Filing to a Regulatory Authority in connection with a Regulatory Meeting shall be subject to Section 3.1.

Section 1.3 **Inspections and Audits**.

(a) If a Regulatory Authority plans to conduct an inspection or audit of Licensee, its relevant Affiliates, Permitted Subcontractors or Study Sites with respect to the

China Study or Licensed Product, Licensee shall, within [***] of the receipt of notice of such inspection or audit (or [***] of the receipt of notice of such inspection or audit if the inspection or audit is scheduled to occur within [***] of the receipt of such notice), notify Company thereof and provide a copy of all written correspondence from such Regulatory Authority regarding the planned inspection or audit. Licensee shall, and shall cause its relevant Affiliates, Permitted Subcontractors and Study Sites to cooperate with Company and the applicable Regulatory Authority with respect to such inspection or audit in accordance with such standard operating procedure(s) to the extent such standard operating standards and the relevant trainings are provided by Company to Licensee in advance and provide all assistance requested by Company with respect thereto, including, upon Company's request, [***] to schedule such inspection or audit to allow representatives of Company to be present during any such inspection or audit (including accommodating Company's attendance, rescheduling or use available extensions). Except to the extent otherwise provided in any standard operating procedure(s) provided by Company to Licensee with respect to an inspection or audit by a Regulatory Authority, following receipt of the inspection or audit observations of the Regulatory Authority, Licensee shall promptly (and, in any event, within [***] of Licensee's receipt thereof) provide a copy to Company (including a copy of the original communication or documentation) and shall provide an English translation thereof (to the extent not already in English) to Company as soon as practicable (and in any event within [***] following Licensee's receipt of such original communication or documentation), and Licensee will prepare, in consultation with Company, any appropriate responses or filings (including filing any remediation plan or responses to findings) with respect thereto in accordance with Section 3.1. For clarity, in accordance with Section 3.1, prior to responding to any applicable Regulatory Authority with respect to such inspection or audit, Licensee shall provide draft responses to Company for review, comment and approval, and Licensee shall not submit any response or filing to any applicable Regulatory Authority in connection with such inspection or audit that has not been approved by Company. Licensee shall maintain complete and accurate records of all such inspections and audits (including the Regulatory Authority's findings and responses thereto) and all remediation or corrective actions planned or taken with respect to any such inspection or audit. If a Regulatory Authority desires to conduct an inspection or audit of Company, its relevant Affiliates or subcontractors, with respect to the China Study, then, upon Company's reasonable request, Licensee shall, and shall cause its applicable Affiliates, Permitted Subcontractors and Study Sites to, cooperate with and assist Company and the Regulatory Authority with respect to such inspection or audit.

(b) Company, by itself or through its Affiliate(s) or designee(s), shall have the right, at Licensee's reasonable cost and expense (no more than [***]), no more than [***] per [***] (other than any for-cause audit), upon reasonable advance notice, and during regular business hours, to (i) inspect the facilities where any quantities of the Licensed Product are stored or handled by Licensee, its Affiliates, Permitted Subcontractors or Study Sites, including any associated books and records, for purposes of verifying Licensee's compliance with this nHCM Supplemental Agreement, (ii) inspect Licensee's, its Affiliates' or Permitted Subcontractors' conduct of the China Study and any Study Sites or laboratories or other testing facilities used by Licensee, its Affiliates or Permitted Subcontractors to conduct any portion of the China Study or testing activities with respect thereto, including any associated books and records (including copies of agreements with Study Sites and Permitted Subcontractors), to observe and verify Licensee's compliance with this nHCM Supplemental Agreement, (iii) review, copy and audit all Study Data generated, maintained or used in connection with Licensee's, its Affiliates', Permitted Subcontractors' or Study Sites' conduct of the China Study or any other activities hereunder, (iv) interview any of Licensee's (or its Affiliates', Permitted

Subcontractors' or Study Sites') personnel involved in the conduct of the China Study or any other activities hereunder, and (v) audit any recordkeeping, data collection and processing, information and other systems and business processes used by or on behalf of Licensee in the conduct of the China Study or any other activities hereunder. Promptly upon Licensee's request, Company shall provide Licensee with reasonable documentation of the cost of any such audit, which documentation shall include an itemized list of costs and expenses for such audit in reasonable detail. Licensee shall, and shall cause its Affiliates, Permitted Subcontractors and Study Sites to, cooperate with any and all activities contemplated by this Section 3.3(b) and shall ensure timely access to requested facilities and documentation. If any such inspection, review or audit identifies an issue with respect to Licensee's, its Affiliates', Permitted Subcontractors' or Study Sites' conduct of the China Study or any other activities hereunder, then, without limitation to any rights or remedies that may be available to Company under this nHCM Supplemental Agreement or the License Agreement, the Parties shall promptly confer and Licensee shall, and shall cause its applicable Affiliates, Permitted Subcontractors or Study Sites to, [***] implement mitigation or remediation measures required by Company at Licensee's cost and expense as soon as reasonably practicable but in any event not more than [***] after the Parties reach such agreement, unless otherwise agreed in writing by the Parties.

Section 1.4 **HGR Filings and Approvals**.

(a) Unless otherwise instructed by Company, Licensee shall file all necessary applications for HGR Approvals for the China Study with the OHGRA to enable Licensee and Company to commence the China Study. In connection with the foregoing, Licensee (i) shall prepare and provide for Company's review and comment sufficiently in advance of (and in any event at least [***] prior to) filing any draft applications for any such HGR Approval in English, including any applications for transferring and sharing of data or information in connection with the China Study, (ii) shall not file any such application that has not been approved by Company, and (iii) shall provide Company with an as-filed copy of any application for HGR Approvals and an English translation thereof (to the extent not already in English) promptly (and in any event within [***]) after submission to the OHGRA. The foregoing sentence shall apply to any amendment applications to any issued HGR Approvals, *mutatis mutandis*. For the avoidance of doubt, Company shall have the right to make all decisions regarding the content of any applications (including amendment applications) for any HGR Approvals with respect to the China Study and Licensee may not delegate preparation of any materials with respect to any such HGR Approvals to any Third Party without prior written approval from Company. Any such Third Party as may be approved by Company shall be deemed a Permitted Subcontractor and subject to the applicable terms and conditions hereunder (including Section 2.3) and under the License Agreement.

(b) Subject to Section 3.4(a), Licensee shall ensure, and shall cause its applicable Affiliates, Permitted Subcontractors and Study Sites, to take all necessary actions to ensure that (i) the collection, use and processing of Study Data in connection with the China Study, (ii) all transferring and sharing of Study Data and any other data and information in connection with the China Study among Licensee, its Affiliates, Permitted Subcontractors, Study Sites, Company, and its Affiliates or designee, and (iii) the Publication of Study Data or other results generated in the course of the conduct of the China Study under this Agreement, in each case ((i) through (iii)), are conducted in accordance with applicable Laws and after having received all requisite approvals from Governmental Authorities in the PRC, including applicable HGR Approval(s), and, upon Licensee's specific reasonable request and at Licensee's sole costs (with respect to internal and external costs and expenses reasonably incurred by Company or its

Affiliates), Company shall, and shall cause its applicable Affiliates, to provide reasonable assistance in furtherance of the foregoing.

Article IV
GOVERNANCE

Section 1.1 **Authority of the JSC**. In addition to its responsibilities set forth in the License Agreement, the JSC shall have the authority to oversee the Development and regulatory activities with respect to the China Study conducted by each Party under this nHCM Supplemental Agreement, and shall be the forum to facilitate information exchange between the Parties with respect to the China Study, including the following responsibilities:

(a) provide a forum for the discussion of the Parties' activities under this nHCM Supplemental Agreement;

(b) oversee activities with respect to the China Study conducted by Licensee, its applicable Affiliates, Permitted Subcontractors and Study Sites under this nHCM Supplemental Agreement, including the review of compliance and quality procedures (including GLP and GCP compliance);

(c) subject to Section 2.2(j), oversee safety and pharmacovigilance issues with respect to the China Study, including any expedited safety reports and recalls with respect thereto;

(d) oversee the participation, to the extent permitted by applicable Laws and as applicable, of any representative or designee of either Party in any open session meeting of the data monitoring committee with respect to the China Study;

(e) review and approve the China Study Development Plan (if the full China Study Development Plan has not been finalized as of the nHCM Supplemental Agreement Effective Date) and any amendments to the Study Guidelines or China Study Development Plan;

(f) review and approve any amendment to the [***] or [***];

(g) if applicable, serve as a forum for the Parties to discuss [***] in the event of a change to the [***] or the [***] as set forth in Section 2.2(b);

(h) resolve any matter with respect to which mutual agreement by the Parties is expressly required hereunder and the Parties are unable to reach such agreement within a reasonable amount of time (or such time as may be expressly specified for such agreement by the Parties);

(i) [***];

(j) review and discuss any dispute over whether Licensee (or its designated Affiliate) may [***]; and

(k) perform such other functions as are assigned to it pursuant to this nHCM Supplemental Agreement or as appropriate to further the purposes of this nHCM Supplemental Agreement to the extent agreed to in writing by Company and Licensee.

Section 1.2 **Development Subcommittee**. Pursuant to Section 5.6(a) of the License Agreement, the Parties will form a joint development committee (the "**JDC**") as soon as practicable, but no later than [***] after the nHCM Supplemental Agreement Effective Date. Notwithstanding anything to the contrary in the last sentence of Section 5.6(a) of the License Agreement, the JSC may delegate specifically-defined responsibilities of the JSC out of those set forth in Section 4.1 to the JDC, for which the JDC will be able to make decisions by unanimous vote by the Parties pursuant to the following sentence. Company's representatives on the JDC will collectively have one vote, Licensee's representatives on the JDC will collectively have one vote, and no decision will be made by the JDC without a unanimous vote by the Parties. Should the JDC not be able to reach agreement with respect to a matter at a duly called meeting of the JDC, at the written request of either Company or Licensee, such matter shall promptly, and in any event within [***] (or [***] in the event of an urgent matter) after such request, be referred to the JSC for resolution as set forth in Section 4.6.

Section 1.3 **Establishment of the Joint Compliance Committee**. Within [***] after the nHCM Supplemental Agreement Effective Date, the JSC will establish a joint compliance committee (the "**Joint Compliance Committee**") under the License Agreement, which will consist of [***] representatives from each of Company and Licensee (or such other equal number of representatives from each of Company and Licensee as the JSC determines is appropriate from time to time), each with the requisite expertise relevant to issues falling within the authority of the Joint Compliance Committee. From time to time, each of Company and the Licensee may substitute one or more of its representatives to the Joint Compliance Committee on written notice to the other. The Joint Compliance Committee will be co-chaired by one designated representative of each of Company and Licensee.

Section 1.4 **Authority of the Joint Compliance Committee**. The Joint Compliance Committee will operate under the supervision and control of the JSC. All compliance activities with respect to Licensee's conduct of the China Study during the Term shall be conducted under the oversight of the Joint Compliance Committee. In addition to its overall responsibility to oversee and address compliance matters for the China Study during the Term, the Joint Compliance Committee will:

(a) oversee and address operational issues associated with the implementation of the Compliance Standards with respect to the Compliance Program as set forth in Section 5.1(b);

(b) oversee and provide input on the implementation of any necessary corrective actions as set forth in Section 5.1(b); and

(c) perform such other functions as appropriate to further the purposes of this nHCM Supplemental Agreement to the extent agreed to in writing by Company and Licensee.

Section 1.5 **Meetings; Minutes**. The Joint Compliance Committee shall hold meetings at such times as Company and Licensee shall determine, but in no event less frequently than each [***] during the Term, commencing from and after the time the Joint Compliance Committee is established as provided herein unless the co-chairpersons agree otherwise. All Joint Compliance Committee meetings may be conducted by telephone, video-conference or in person as determined by mutual agreement of the co-chairpersons. Unless otherwise agreed by the Parties, all in-person meetings of the Joint Compliance Committee shall be held at Company's or its Affiliates' facilities. Further, in addition to the regularly scheduled meetings,

the Joint Compliance Committee shall meet upon the reasonable request of the co-chairpersons or either Company's or Licensee's co-chairperson, as applicable. In addition, each of Company and Licensee may from time to time invite a reasonable number of participants, in addition to its representatives, to attend the Joint Compliance Committee meetings in a non-voting capacity; provided that if either Company or Licensee intends to have any Third Party (including any consultant) attend such a meeting, such Party will [***]. Such Party will also ensure that such Third Party is bound by confidentiality and non-use obligations no less stringent than those set forth in ARTICLE VIII of the License Agreement. Either Company's or the Licensee's co-chairperson may call a special meeting of the Joint Compliance Committee upon at least [***] prior written notice, except that emergency meetings may be called with at least [***] prior written notice. Any alternative agreement of Company and the Licensee or the applicable co-chairpersons with respect to Joint Compliance Committee meetings under this Section 4.5 shall be in writing. The co-chairpersons shall be responsible for preparing and circulating an agenda in advance of each meeting and preparing and issuing final minutes within [***] thereafter.

Section 1.6 **Decision-Making**.

(a) In the case of any matter that cannot be resolved by the Joint Compliance Committee, at the written request of either Company or the Licensee, such matter shall promptly, and in any event within [***] (or [***] in the event of an urgent matter) after such request, be referred to the JSC with a written request for resolution in accordance with the procedure set forth in the License Agreement.

(b) Without limitation of the matters for which the Senior Officer of Company has final decision-making authority pursuant to Section 5.5 of the License Agreement, during the Term, the Senior Officer of Company shall have final decision-making authority with respect to any matter that is within the responsibilities of the Joint Compliance Committee.

(c) Should the JSC be unable to reach agreement with respect to a matter relating to the China Study at any duly called meeting of the JSC, at the written request of either Company or Licensee, such matter shall promptly, and in any event within [***] (or [***] in the event of an urgent matter) after such request, be referred to the Senior Officers for resolution, and the Senior Officers will attempt to resolve the matter promptly in good faith. If the Senior Officers fail to resolve a matter within [***] after the date on which such matter is first referred to the Senior Officers (unless a longer period is agreed to by Company and Licensee) under the License Agreement, then, notwithstanding any provisions of Section 3.5(b)(ii) of the License Agreement and Section 5.5 of the License Agreement that would provide otherwise, the Senior Officer of Company will have the final decision-making authority, without any further resort to any other dispute resolution mechanism, on all matters that are [***]; *provided* that [***]. For clarity, (A) Company's final decision-making authority in the foregoing sentence shall be in addition to Company's final decision-making authority provided under Section 3.6 and Section 5.5 of the License Agreement and shall not be subject to any limitation on Company's final decision-making authority set forth in Section 5.5 of the License Agreement or any exception with respect to resolving a Regulatory Deadlock under the License Agreement and (B) without limitation to any final decision-making authority or approval or other right of Company under the [***], License Agreement or any Ancillary Agreement, once [***] as set forth in Section 2.2(c), Company's final decision-making authority set forth in this Section 4.6(c) shall [***].

(d) For clarity, (i) [***] and (ii) the matters subject to Company's final decision-making authority shall not be eligible for resolution by binding arbitration in accordance with Section 13.2 of the License Agreement.

(e) Notwithstanding any provision of this Article IV to the contrary, the JSC will not have the authority to amend, modify, or waive compliance with, the terms or conditions of this nHCM Supplemental Agreement.

(f) Licensee shall, and shall ensure that its Representatives, conduct all activities in compliance with Company's final decisions.

Article V
COMPLIANCE

Section 1.1 **Compliance Program**.

(a) During a period of [***] (or such longer period as may be mutually agreed by the Parties (through the JSC or in writing)) following the nHCM Supplemental Agreement Effective Date, Company shall have the right to conduct due diligence of Licensee's existing compliance policies and related internal controls, in each case, solely with respect to Licensee's conduct of the China Study, and Licensee shall cooperate in good faith and facilitate any such due diligence, including providing relevant documentation and communications to Company in a timely manner and making appropriate Licensee personnel available for discussions with respect thereto. If Company commences any such due diligence, Company shall [***] provide Licensee a written summary of the due diligence findings and recommendations promptly after completion of such due diligence.

(b) As soon as reasonably practicable after the nHCM Supplemental Agreement Effective Date, Licensee shall establish and implement (or if one has already been established and implemented, confirm to Company that it has established and implemented) a compliance program solely with respect to Licensee's conduct of the China Study, (such program, the "**Compliance Program**"), based on the standards and principles that are set forth on **Exhibit 5.1** attached hereto and made part of this nHCM Supplemental Agreement (the "**Compliance Standards**") and satisfactory implementation of any recommendations of Company consistent with the Compliance Standards that arise from any due diligence conducted by Company pursuant to Section 5.1. Licensee shall promptly notify Company after it has implemented any such recommendations of Company and in any event if Licensee reasonably believes the Compliance Program has been established and implemented in accordance with the Compliance Standards and is ready for Company's review and approval. After receipt of Licensee's notice, Company shall promptly determine in good faith whether the Compliance Program has been established in accordance with the Compliance Standards and all associated applicable Laws and shall provide written approval of the Compliance Program to Licensee if it reasonably makes such an affirmative determination (a "**Compliance Program Confirmation**"). The Joint Compliance Committee shall oversee and address any operational issues associated with the implementation of the Compliance Standards with respect to the Compliance Program. The Licensee shall, subject to oversight and input from the Joint Compliance Committee, implement any necessary corrective actions identified by Company as a result of its review pursuant to this Section 5.1(b). Company will have the right to audit Licensee's compliance activities with respect to the China Study upon reasonable advanced notice, and during regular business hours, and no more frequently than [***] in any consecutive [***].

(c) Unless otherwise instructed by Company in writing, Licensee will not commence any activities related to any portion of the China Study (except any activities as agreed by the Joint Compliance Committee) prior to the later of (i) the completion of Company's due diligence pursuant to Section 5.1(a), and (ii) Licensee's receipt from Company of the Compliance Program Confirmation.

Section 1.2 **Periodic Certifications**. Without limitation to the foregoing, Licensee will be required to submit certifications of compliance with Compliance Standards and the relevant policies and procedures as set forth in this nHCM Supplemental Agreement at the frequency required by Company, but at least [***] during the Term (or, with respect to the [***], for so long as the [***]), in substantially the form of **Exhibit 5.2** attached hereto.

Section 1.3 **Compliance Training**. In furtherance of the Compliance Program, Licensee shall establish a reasonable compliance training program for Licensee personnel, and Company or its designee shall, at Licensee's reasonable request, provide personnel (such Company personnel, the "**Company Trainers**") to provide a one-time training to Licensee personnel assigned to train other personnel of Licensee on compliance matters (such Licensee personnel, the "**Licensee Trainers**") so that the Licensee Trainers can conduct similar compliance training to Licensee representatives on an ongoing basis. Licensee will provide Company with documentation that the training occurred, and will bear all costs of such training, including the out-of-pocket costs of training the Licensee Trainers (but not Company's internal costs associated with Company employees). In addition, Licensee will provide Licensee personnel with periodic training (including the training on the policies included in the Compliance Standards) and will provide to Company, upon Company's request, documentation that evidences that Licensee personnel have been properly trained in accordance with the foregoing. No Person will perform any activity related to this nHCM Supplemental Agreement unless and until they have been is trained about compliance related matters and the policies and procedures related to the activities in which they are engaged.

Section 1.4 **Compliance with Anti-Corruption Laws**. Notwithstanding anything to the contrary in this nHCM Supplemental Agreement, Licensee agrees that (a) it shall not, and shall cause its Affiliates, Sublicensees and Permitted Subcontractors and Study Sites not to, in the performance of this nHCM Supplemental Agreement, perform any actions that are prohibited by applicable Laws relating to anti-corruption (including the provisions of the United States Foreign Corrupt Practices Act, collectively "**Anti-Corruption Laws**") that may be applicable to one or both Parties, either Party's Affiliates or its Sublicensees; (b) it shall not, and shall cause its Affiliates, Sublicensees and Permitted Subcontractors and Study Sites not to, in the performance of this nHCM Supplemental Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws; and (c) it shall, and shall cause its Affiliates, Sublicensees and Permitted Subcontractors and Study Sites to, maintain records (financial and otherwise) and supporting documentation related to the subject matter of this nHCM Supplemental Agreement in order to document or verify compliance with the provisions of this Section 5.4.

Article VI
CONFIDENTIALITY AND PUBLICATION

Section 1.1 **Confidentiality**. The Parties acknowledge and agree that any trade secrets or confidential or proprietary information disclosed by or on behalf of a Party to the other Party under or in connection with this nHCM Supplemental Agreement that would constitute Confidential Information under the License Agreement if disclosed thereunder shall be deemed to be Confidential Information of such Party hereunder and under the License Agreement, and Article VIII of the License Agreement shall apply, *mutatis mutandis*, with respect to such Confidential Information. Notwithstanding anything to the contrary herein or in the License Agreement, (a) Study Data, China Study Regulatory Filings, Global Study Data and Filings, Study Guidelines and the China Study Development Plan shall be deemed to be Company's Confidential Information (subject to Confidentiality Exceptions), and Company shall be deemed to be the disclosing Party, and Licensee shall be deemed to be the receiving Party, with respect thereto.

Section 1.2 **Publication**. Notwithstanding anything to the contrary herein or in the License Agreement (including Section 8.2 thereof):

(a) Licensee shall not, and shall cause its Affiliates not to, publish, present or otherwise publicly disclose the Study Data or any other data from the Global Clinical Study without Company's prior written consent [***], and thereafter, Licensee's right to publish, present or otherwise publicly disclose the Study Data or any other data from the Global Clinical Study shall be subject to the terms of Section 6.2(b) below.

(b) [***]. In the event that [***] proposes to publish or present the Study Data [***] in a Publication [***] or its Affiliate(s), [***] will provide to [***] the opportunity to [***] a draft of such proposed Publication. [***] will provide its comments on such proposed Publication in writing promptly and in no event later than (a) [***] prior to the intended submission of a manuscript for publication or (b) [***] prior to the intended presentation or submission of an abstract. [***] shall [***], but, subject to Section 6.2(a), shall [***]; *provided* that (A) [***] will remove from such proposed Publication any Confidential Information of [***] as requested by [***], (B) in the event [***] needs to seek patent protection related to information contained in such proposed Publication, [***] such Publication, or, in the case of presentation, make such presentation, until [***] is given a reasonable period of time (in any event, not to exceed [***]) to seek patent protection for any material in such Publication that it believes is patentable and has the right to seek patent protection therefor, and (C) [***], prior to the intended submission or presentation (as the case may be) of such Publication, [***]. In addition, [***] shall abide by the standards and guidelines, as amended from time to time, promulgated by the International Committee of Medical Journal Editors (ICMJE) and good publication practice (GPP3) with regard to scientific publications and presentations.

Article VII
REPRESENTATIONS, WARRANTIES AND COVENANTS

Section 1.1 **Mutual Representations and Warranties**. Each Party represents and warrants to each other Party that, as of the nHCM Supplemental Agreement Effective Date:

(a) It is duly organized, validly existing, and in good standing under the applicable Laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this nHCM Supplemental Agreement.

(b) It has full right, power and authority to enter into this nHCM Supplemental Agreement and to perform its respective obligations under this nHCM Supplemental Agreement, and this nHCM Supplemental Agreement and the performance by such Party of this nHCM Supplemental Agreement do not violate such Party's charter documents, bylaws or other organizational documents.

(c) Except for any approvals necessary for the Development of Licensed Products (e.g., approvals for CTAs and HGR Approvals) [***], all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this nHCM Supplemental Agreement have been obtained.

(d) It is not under any obligation, contractual or otherwise, to any Person that would materially affect the diligent and complete fulfillment of obligations under this nHCM Supplemental Agreement and the execution and delivery of this nHCM Supplemental Agreement by such Party, and the performance of such Party's obligations under this nHCM Supplemental Agreement (as contemplated as of the nHCM Supplemental Agreement Effective Date) (i) does not conflict with or violate any requirement of applicable Laws, (ii) does not conflict with or violate any order, writ, judgment, injunction, decree, determination, or award of any court or Governmental Authority presently in effect applicable to such Party, and (iii) does not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates.

(e) This nHCM Supplemental Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar applicable Laws affecting the enforcement of creditors' rights generally.

Section 1.2 **No Debarment**. Each Party acknowledges and agrees that Section 9.4 of the License Agreement shall apply to activities under this nHCM Supplemental Agreement. Without limitation to the foregoing, each Party represents and warrants that neither it nor any of its Affiliates has employed or otherwise used in any capacity, or will employ or otherwise use in any capacity in connection with the activities to be performed under this nHCM Supplemental Agreement, any Person suspended, proposed for debarment, or debarred under any foreign equivalent of Section 306 of the FFDCA, including the disqualification provisions of the Drug Administration Law or PRC Regulation on the Administration of Human Genetic Resources in the Territory and related regulations and rules, in performing any portion of its obligations hereunder.

Section 1.3 **NO OTHER WARRANTIES**. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS NHCM SUPPLEMENTAL AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTY OF ANY KIND UNDER THIS SUPPLEMENTAL AGREEMENT, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL

REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS NHCM SUPPLEMENTAL AGREEMENT).

Article VIII
INDEMNIFICATION

Section 1.1 **Indemnification and Indemnification Procedures**. ARTICLE X of the License Agreement shall apply, *mutatis mutandis*, with respect to all activities under this nHCM Supplemental Agreement; provided that Licensee's indemnification obligation under Section 10.2(d) of the License Agreement shall also apply to any Third Party Losses incurred by a Company Indemnified Party to the extent resulting from Company's status as the Sponsor and holder of the CTA for the China Study.

Section 1.2 **Limitation of Liability**.

(a) NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES OR FOR ANY LOST PROFITS ARISING OUT OF THIS NHCM SUPPLEMENTAL AGREEMENT, IN EACH CASE HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

(b) THE LIMITATIONS AND DISCLAIMER SET FORTH IN SECTION 8.2(A) WILL NOT APPLY TO A CLAIM (A) FOR WILLFUL MISCONDUCT; (B) FOR A BREACH OF ARTICLE VI; OR (C) FOR INDEMNIFIABLE LOSSES PURSUANT TO SECTION 8.1.

Article IX
TERM AND TERMINATION

Section 1.1 **Term**. This nHCM Supplemental Agreement shall become effective as of the nHCM Supplemental Agreement Effective Date and, unless earlier terminated in accordance with the terms hereof, shall expire upon the earliest of (a) the expiration of the License Agreement in accordance with the terms therein, (b) the submission of the Regulatory Approval Application of the Licensed Product in the PRC for nHCM, (c) completion of the China Study in accordance with the Study Guidelines or (d) termination of the China Study (the "**Term**").

Section 1.2 **Termination for Material Breach**. Subject to Section 9.3, upon any material breach of this nHCM Supplemental Agreement by (a) Company or (b) Licensee, or upon a Curable Compliance Failure by Licensee (the Party allegedly breaching being the "**Breaching Party**"), the other Party (the "**Non-Breaching Party**") will have the right, but not the obligation, to terminate this nHCM Supplemental Agreement in its entirety by providing written notice to the Breaching Party, which notice will in each case (i) expressly reference this Section 9.2, (ii) reasonably describe the alleged breach which is the basis of such termination, and (iii) clearly state the Non-Breaching Party's intent to terminate this nHCM Supplemental Agreement if the alleged breach is not cured within the applicable cure period set forth in the notice, which cure period will not in any event be less than [***] (or [***] in the case of a Curable Compliance Failure). The final two sentences of Section 12.3(a) of the License Agreement shall apply, *mutatis mutandis*, with respect to the right to terminate this nHCM

Supplemental Agreement pursuant to this Section 9.2. For clarity, a material breach of this nHCM Supplemental Agreement or a Curable Compliance Failure shall [***], unless such material breach of this nHCM Supplemental Agreement or Curable Compliance Failure [***], in which case, the [***]. For clarity, if (x) there is a dispute under both this nHCM Supplemental Agreement and the License Agreement as to whether there has been a material breach, whether such material breach is reasonably curable within the applicable cure period, or whether such material breach or a Curable Compliance Failure has been cured within the applicable cure period and (y) such dispute raises issues or facts that are substantially the same or connected, then the Non-Breaching Party may elect for such dispute to be a Connected Dispute (such election to be notified to the Breaching Party) and require that any binding arbitration be conducted solely pursuant to either this nHCM Supplemental Agreement or the License Agreement. If binding arbitration is conducted pursuant to this nHCM Supplemental Agreement, any ruling by the arbitrators in such binding arbitration with respect to the License Agreement dispute shall be considered final under the License Agreement as if such binding arbitration had been conducted pursuant to Section 13.2 of the License Agreement and if binding arbitration is conducted pursuant to the License Agreement, any ruling by the arbitrators in such binding arbitration with respect to the dispute under this nHCM Supplemental Agreement shall be considered final under this nHCM Supplemental Agreement as if such binding arbitration had been conducted pursuant to Section 10.2(b). For clarity, Licensee does not have the right to dispute whether a particular act or omission constitutes a Curable Compliance Failure, which determination shall be made by Company as set forth in this Section 9.2. The termination will become effective at the end of the applicable cure period unless the Breaching Party cures such breach during the applicable cure period [***]. For purpose of this Section 9.2, a Compliance Failure shall be deemed to be a material breach of this nHCM Supplemental Agreement by Licensee. "**Compliance Failure**" means [***]. "**Curable Compliance Failure**" means a Compliance Failure, that Company determines, in its sole and reasonable discretion, is a single, independent, non-systematic, and non-repetitive administrative error, delay or oversight.

Section 1.3 **Termination for Failure to Establish and Implement a Compliance Program**. Company will have the right to terminate this nHCM Supplemental Agreement and, with respect to the China Study, any Ancillary Agreement, effective immediately upon written notice to Licensee, if Licensee fails to establish or implement a Company approved Compliance Program in accordance with Section 5.1.

Section 1.4 **Termination Due to Termination of the License Agreement**. This nHCM Supplemental Agreement shall automatically terminate in the event the License Agreement is terminated.

Section 1.5 **Termination Due to Termination of the China Study by Company**. This nHCM Supplemental Agreement shall automatically terminate in the event Company terminates the China Study in accordance herewith.

Section 1.6 **Effect of Expiration or Termination**.

(a) Upon termination or expiration of this nHCM Supplemental Agreement, the Parties' rights and obligations under this nHCM Supplemental Agreement will terminate and neither Company nor Licensee will have any further rights or obligations under this nHCM Supplemental Agreement from and after the effective date of termination, except as set forth in this Section 9.6.

(b) Upon termination of this nHCM Supplemental Agreement under Section 9.2, Section 9.3 or Section 9.4, in each case, without limiting any other rights and remedies that may be available to Company and subject to Section 9.6(c) and Section 9.6(d), Company shall have the right, in its sole discretion, to decide whether to continue the China Study or terminate the China Study.

(c) In the event that Company elects to continue the China Study in accordance with Section 9.6(b):

(i) [***]

(ii) [***]

(iii) [***]

(iv) [***]

(v) the Parties shall amend the Ancillary Agreements as necessary to remove from the scope of such agreements the subject matter of this nHCM Supplemental Agreement.

(vi) [***]

(vii) [***]

(viii) [***]

(d) In the event that Company elects to terminate the China Study in accordance with Section 9.6(b) or in the event that this nHCM Supplemental Agreement is terminated under Section 9.5:

(i) the Parties shall terminate the conduct of the China Study with due regard for patient safety and the rights of any subjects that are participants in the China Study, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable Laws; and

(ii) Licensee shall work and coordinate with Company in good faith to terminate the China Study and provide such assistance and cooperation as may be necessary or reasonably requested by Company or its designee, including notifications, filings and submissions to and communications with the applicable Regulatory Authorities.

(e) Upon termination or expiration of this nHCM Supplemental Agreement, Section 12.4(j) of the License Agreement shall apply, *mutatis mutandis*, with respect to any Confidential Information disclosed under or in connection with this nHCM Supplemental Agreement.

(f) The expiration or termination of this nHCM Supplemental Agreement shall be without prejudice to any rights or obligations of the Parties that may have accrued prior to such expiration or termination.

(g) Upon expiration or termination of this nHCM Supplemental Agreement, any term that by its nature is intended to survive expiration or termination of this nHCM Supplemental Agreement shall so survive, including: Article I (Definitions) (to the extent necessary to construe the other surviving provisions), Section 2.1(d), the sixth sentence of Section 2.2(c) together with the [***] (solely with respect to the [***] and only for so long as the [***]), Section 2.4 (Costs and Expenses) (with respect to any unpaid amount accrued prior to such expiration or termination or as set forth in [***]), Section 2.8 (Study Data) (except for the first four sentences thereof [***]), Section 2.9 (Good Data Practice) (for so long as any Study Data is in the possession of control of Licensee or any of its Affiliates, Permitted Subcontractors or, unless the conduct of the China Study has been completely transitioned from Licensee or its applicable Affiliate(s) or Permitted Subcontractor(s) to Company as provided in Section 9.6(c), Study Sites), Section 3.1(a) (solely with respect to the first sentence thereof), Article VI (Confidentiality and Publication), Section 7.3 (No Other Warranties), Article VIII (Indemnification), this Section 9.6 (Effect of Expiration or Termination), and Article X (Miscellaneous).

Article X
MISCELLANEOUS

Section 1.1 **Assignment; Change of Control of Licensee**.

(a) This nHCM Supplemental Agreement and the rights and obligations of either Party under this nHCM Supplemental Agreement will not be assignable, delegable, transferable, pledged or otherwise disposed of by either Party except in connection with a permitted assignment of the License Agreement pursuant to the terms thereof. If either Party assigns the License Agreement to a Third Party pursuant to the terms of the License Agreement, then such Party shall also assign this nHCM Supplemental Agreement to such Third Party.

(b) During the Term, (i) without the prior written consent of Company, no Licensee Party shall effect, or authorize or enter into any agreement to effect, a Change of Control, where the Acquirer is not a [***], whether through a transaction or a series of related transactions, and (ii) in any case, no Licensee Party shall effect a Change of Control, whether through a transaction or a series of related transactions, unless, [***].

Section 1.2 **Governing Law; Dispute Resolution**.

(a) **Governing Law**. This nHCM Supplemental Agreement shall be governed and interpreted in accordance with the law of the State of New York, United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this nHCM Supplemental Agreement to the substantive law of another jurisdiction.

(b) **Dispute Resolution**. Any claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of this nHCM Supplemental Agreement will be resolved in accordance with Article 13 of the License Agreement, *mutatis mutandis*, and the provisions of Article 13 of the License Agreement are hereby incorporated by reference in this nHCM

Supplemental Agreement. For clarity, (i) if any matter is within the scope of the JSC's authority, the provisions of Section 4.6 of this nHCM Supplemental Agreement will initially apply with respect to such matter; and (ii) if this nHCM Supplemental Agreement expressly provides that a matter is subject to a Party's discretion or a Party's sole or final decision-making authority, such matter will not be subject to dispute resolution under this Section 10.2(b) or Article 13 of the License Agreement, but may be finally determined by such Party in accordance with the terms of this nHCM Supplemental Agreement.

(c) **Connected Disputes**. It is the expectation of the Parties that there may be disputes that arise under the License Agreement that are likely to be related to (or the source of) a dispute or disagreement under this nHCM Supplemental Agreement, or raise issues or facts that are substantially the same as or connected with issues or facts raised in a dispute under this nHCM Supplemental Agreement (a "**Connected Dispute**"). Accordingly, notwithstanding anything to the contrary in the License Agreement, during the Term, the Parties undertake to each other that they shall not, and shall procure that their respective relevant Affiliates shall not, initiate or otherwise commence any arbitration proceedings under Section 13.2 of the License Agreement with respect to a Connected Dispute and shall, instead, seek to resolve such Connected Dispute in accordance with Section 10.2(b) and the terms of this nHCM Supplemental Agreement; provided that, with respect to any Connected Dispute that arises from a breach or alleged breach of either Party, the Non-Breaching Party may elect for such Connected Dispute (such election to be notified to the Breaching Party) be submitted to binding arbitration solely pursuant to either this nHCM Supplemental Agreement or the License Agreement as set forth in Section 9.2.

Section 1.3 **Notices**. Any notice or report required or permitted to be given or made under this nHCM Supplemental Agreement by one Party to any other Party will be in writing and will be deemed to have been delivered (a) upon personal delivery (upon written confirmation of receipt), (b) when received by the addressee, if sent by a reputable, internationally recognized overnight courier that maintains records of delivery, (c) by email delivery (upon written confirmation of receipt), and (d) in the case of notices provided by telecopy (which notice will be followed immediately by an additional notice pursuant to clause (a) or (b) above if the notice is of a default under this nHCM Supplemental Agreement), upon completion of transmission, with transmission confirmed, to the addressee's facsimile machine, as follows (or at such other addresses or facsimile numbers as may have been furnished in writing by a Party to another Party as provided in this Section 10.3). This Section 10.3 is not intended to govern the day-to-day business communications necessary among the Parties in performing their obligations under the terms of this nHCM Supplemental Agreement:

If to Company to:	MyoKardia, Inc. [***]
With a copy (which shall not constitute notice) to:	[***]
If to Licensee to:	LianBio Licensing, LLC 103 Carnegie Center Drive Suite 215, Princeton, NJ 08540 Attention: Yizhe Wang, Manager Email: Yizhe.Wang@lianbio.com and Lian Cardiovascular Limited Rooms 05-15, 13A/F, South Tower, World Finance Centre, Harbour City, 17 Canton Road, Tsim Sha Tsui, Kowloon, Hong Kong Attention: Yizhe Wang, Director Email: Yizhe.Wang@lianbio.com
With a copy (which shall not constitute notice) to:	Ropes & Gray LLP 36F Park Place 1601 Nanjing Road West Shanghai, China 200040 Attention: Eric Wu Fax: 86-21-6157-5299 Email: Eric.Wu@ropesgray.com

Section 1.4 **Severability**. In the event that one or more provisions of this nHCM Supplemental Agreement is held invalid, illegal or unenforceable in any respect, then such provision will not render any other provision of this nHCM Supplemental Agreement invalid or unenforceable, and all other provisions will remain in full force and effect and will be enforceable, unless the provisions that have been found to be invalid or unenforceable will substantially affect the remaining rights or obligations granted or undertaken by any Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision.

Section 1.5 **Entire Agreement; Amendment**. This nHCM Supplemental Agreement, including the Exhibits attached hereto, and together with the License Agreement, [***], PV Agreement, Clinical Quality Agreement and Development Supply Agreement, set forth and constitute the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby (for clarity, excluding the License Agreement (subject to Section 2.1(d)). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment or modification of this nHCM Supplemental Agreement shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

Section 1.6 **Waiver**. The failure of any Party to assert a right under this nHCM Supplemental Agreement or to insist upon compliance with any term or condition of this nHCM Supplemental Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The exercise by either Party of any right or election under the terms or covenants herein will not preclude or prejudice the other Party from exercising the same or any other right it may have under this nHCM Supplemental Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver.

Section 1.7 **Independent Contractors**. No Party will have any responsibility for the hiring, firing or compensation of any other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. For all purposes, and notwithstanding any other provision of this nHCM Supplemental Agreement to the contrary, as between the Parties, each Party's legal relationship under this nHCM Supplemental Agreement to the other Party will be that of independent contractor, and the relationship between the Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes, except as otherwise required by applicable Laws or, solely with respect to the Local Regulatory Agent, as expressly provided otherwise herein.

Section 1.8 **Force Majeure**. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this nHCM Supplemental Agreement for failure or delay performing any obligation under this nHCM Supplemental Agreement to the extent that such failure or delay is caused by or results from a Force Majeure Event and for so long as such failure or delay continues to be caused by or result from such Force Majeure Event. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the nHCM Supplemental Agreement Effective Date may be invoked as a Force Majeure Event for the purposes of this nHCM Supplemental Agreement even though the pandemic is ongoing solely to the extent those effects are not reasonably foreseeable by the Parties as of the nHCM Supplemental Agreement Effective Date. The affected Party will notify the other Party in writing of any Force Majeure Event that may affect its performance under this nHCM Supplemental Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under this nHCM Supplemental Agreement is expected to continue based on currently available information, and will undertake Diligent Efforts to mitigate and overcome such Force Majeure Event and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure Event continues, then the affected Party will update such notice to the other Party on a [***] basis to provide updated summaries of its mitigation efforts and its estimates of when normal performance under this nHCM Supplemental Agreement will be able to resume.

Section 1.9 **No Benefit to Third Parties**. The representations, warranties, covenants and agreements set forth in this nHCM Supplemental Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights on any other Person. This nHCM Supplemental Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than the Licensee Indemnified Parties and the Company Indemnified Parties under Article VIII.

Section 1.10 **Remedies**. The rights and remedies provided herein are cumulative and each Party retains all remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief, with respect to any breach of this nHCM Supplemental Agreement. Neither Party will be required (but, for clarity, will have the right as specified in this nHCM Supplemental Agreement) to terminate this nHCM Supplemental Agreement due to a breach of this nHCM Supplemental Agreement by the other Party.

Section 1.11 **Construction**. Unless the context of this nHCM Supplemental Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this nHCM Supplemental Agreement; (d) the terms "Article," "Section" or "Exhibit" refer to the specified Article, Section or Exhibit of this nHCM Supplemental Agreement; (e) the term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or"; (f) the term "including" or "includes" means "including without limitation" or "includes without limitation"; (g) the word "will", when used in context to indicate an obligation, duty, or requirement of a Person, will be construed to have the same meaning and effect as the word "shall"; and (h) references to any agreement, instrument or other document in this nHCM Supplemental Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto. Whenever this nHCM Supplemental Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified. The captions of this nHCM Supplemental Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this nHCM Supplemental Agreement or the intent of any provision contained in this nHCM Supplemental Agreement. The language of this nHCM Supplemental Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

Section 1.12 **Further Assurances**. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as any other Party may reasonably request in connection with this nHCM Supplemental Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this nHCM Supplemental Agreement.

Section 1.13 **Counterparts**. This nHCM Supplemental Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if all Parties have not executed the same counterpart. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

Section 1.14 **Ambiguities; No Presumption**. Each of the Parties acknowledges and agrees that this nHCM Supplemental Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this nHCM Supplemental Agreement or any provision hereof, no presumption will

apply against any Party as being responsible for the wording or drafting of this nHCM Supplemental Agreement or any such provision, and ambiguities, if any, in this nHCM Supplemental Agreement will not be construed against any Party under the rule of construction, irrespective of which Party may be deemed to have authored the ambiguous provision.

Section 1.15 **Export Control**. This nHCM Supplemental Agreement is made subject to any restrictions required by applicable Laws concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technology licensed to it or other technical information acquired from the other Party under this nHCM Supplemental Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, except in compliance with U.S. export Laws and regulations.

Section 1.16 **English Language.** The language of this nHCM Supplemental Agreement will be written and executed in the English language, and the English language will control its interpretation. In addition, all notices required or permitted hereunder, and all written, electronic, oral or other communication between the Parties regarding this nHCM Supplemental Agreement or any dispute or controversy arising out of it, shall be in the English language. Except as otherwise expressly provided herein, for any Regulatory Filings, communications or other documents that Licensee is required to provide to the Company pursuant to the terms hereunder, if such Regulatory Filings, communications or other documents are not originally received or prepared in the English language, then Licensee shall, at its own cost and expense, provide such documents in their original language, together with English translation of such documents.

[*Signature Page Follows***]**

IN WITNESS WHEREOF, the Parties have executed this nHCM Supplemental Agreement as of the nHCM Supplemental Agreement Effective Date.

MyoKardia, Inc.
By: Pat Gliha

Name: Pat Gliha
Title: Executive Director

LianBio
By: Yizhe Wang

Name: Yizhe Wang
Title: Chief Executive Officer

LianBio Licensing, LLC
By: Yizhe Wang

Name: Yizhe Wang
Title: Manager

Lian Cardiovascular Limited
By: Raphael Ho

Name: Raphael Ho
Title: Director

Shanghai LianBio Development Co., Ltd.
By: Yizhe Wang

Name: Yizhe Wang
Title: Legal Representative

Exhibit 2.2(e)

Form Clinical Trial Agreement

[***]

Exhibit 2.3

Permitted Subcontractors

[***]

Exhibit 5.1
Compliance Standards
[***]

Exhibit 5.2

Form of Certification

[***]

Appendix A to Compliance Certification

Disclosed Findings and Violations

[***]

Exhibit 31.1

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

I, Yizhe Wang, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: November 13, 2023

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Yi Larson, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: November 13, 2023

By: /s/ Yi Larson

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of LianBio (the "Company") for the quarterly period ended September 30, 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: November 13, 2023

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of LianBio (the "Company") for the quarterly period ended September 30, 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: November 13, 2023

By: /s/ Yi Larson

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