UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q/A

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40947

LianBio

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands **(State or other jurisdiction of incorporation or organization)**	**98-1594670** **(I.R.S. Employer Identification No.)**
103 Carnegie Center Drive, Suite 309 **Princeton, NJ** **(Address of principal executive offices)**	**08540** **(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, $0.000017100448 par value 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 ☐ No ☒

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 ☒ No ☐

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of December 1, 2021, 107,238,910 ordinary shares of the registrant, par value $0.000017100448 per share, were outstanding, of which 20,906,116 ordinary shares were held in the form of American Depositary Shares.

Table of Contents

EXPLANATORY

This Amendment No. 1 to the Quarterly Report on Form 10-Q is being filed solely to furnish the Interactive Data files as Exhibit 101 and 104, in accordance with Rule 405 of Regulation S-T. This Amendment does not reflect any events occurring subsequent to the filing date of the original Form 10-Q for the quarter ended September 30, 2021 or in any way modify or update disclosures made in the original Form 10-Q filing for the quarter ended September 30, 2021.

Table of Contents

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 that will contribute to our success in sourcing value and creating partnerships to enable us to build out a broad and clinically validated pipeline;
- our ability to design, initiate and complete any clinical trials to advance our current product candidates, including mavacamten, TP-03, NBTXR3, infigratinib, BBP-398, LYR-210, omilancor, NX-13 and sisunatovir, as well as any future product candidates, towards regulatory approval in China;
- 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;
- 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 a 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 third parties 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 and the markets and communities in which we and our partners, collaborators and vendors operate;
- our estimates of our expenses, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

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

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

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

Risk Factors Summary

Our business is subject to a number of risks that are discussed more fully in the "Risk Factors" section of this Quarterly Report on Form 10-Q. These risks include the following:

- China's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.
- Although the audit report included in our final prospectus dated October 31, 2021 and filed with the Securities and Exchange Commission (the "SEC") on November 2, 2021 is prepared by U.S. auditors who are currently inspected by the Public Company Accounting Oversight Board (the "PCAOB"), there is no guarantee that future audit reports will be prepared by auditors inspected by the PCAOB and, as such, in the future investors may be deprived of the benefits of such inspection. Furthermore, trading in our securities may be prohibited under the Holding Foreign Companies Accountable Act (the "HFCA Act") if the SEC subsequently determines our audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely or the SEC identifies us as a Commission-Identified Issuer, and as a result, U.S. national securities exchanges, such as the Nasdaq, may determine to delist our securities. In addition, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act, which, if enacted, would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three.
- Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act.
- The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs. For additional information regarding the risks associated with having the majority of our operations in China, see "Risk Factors—Risks Related to Doing Business in China and Our International Operations."
- Both recent and future economic, political and social conditions, as well as governmental policies and regulatory actions implemented in China, could affect our ability to operate our business. The Chinese government has provided new guidance on China-based companies raising capital outside of China. Due to our extensive operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with extensive operations in China could adversely affect our business, results of operations and the market price of our ADSs.
- Changes in the legal, political and economic policies of the Chinese government, the relations between China and the United States, or Chinese or United States regulations may materially and adversely affect our business, financial condition, results of operations and the market price of our ADSs, which could cause the value of our ADSs to significantly decline or to become worthless. Any such changes may take place quickly and with very little notice. Recent statements made and regulatory actions undertaken by China's government, including the recent enactment of the Data Security Law of the People's Republic of China (the "Data Security Law"), as well as our obligations to comply with China's Cybersecurity Review Measures (revised draft for public consultation), regulations and guidelines relating to the multi-level protection scheme, the Personal Information Protection Law of the People's Republic of China (the "Personal Information Protection Law") and any other future laws and regulations may require us to incur significant expenses and could materially affect our ability to conduct our business, accept foreign investments, list on a foreign exchange or stay listed on Nasdaq. For additional information, see "Risk Factors—Risks Related to Doing Business in China and Our International Operations."
- We are not currently required to obtain approval or prior permission from the China Securities Regulatory Commission (the "CSRC") or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to conduct a public offering in foreign capital markets. As there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented by the CSRC or any other Chinese regulatory authority, there can be no assurance that we will not be subject to such requirements, approvals or permissions in order to continue our operations in the future. We are required to obtain business licenses from Chinese authorities in connection with our general business activities currently conducted in China.
- The Chinese government may exert more oversight and control over offerings that are conducted overseas and foreign investment in China-based issuers, which could significantly limit or completely hinder our ability to continue to offer our ADSs to investors and could cause the value of our ADSs to significantly decline or become worthless.
- Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our product candidates.
- We have incurred significant losses since our incorporation, have not generated any revenue from product sales to date and anticipate that we will continue to incur losses in the future and may never achieve or maintain profitability.

- We will likely need substantial additional funding for our future in-licensing and product development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.
- We have a very limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are heavily dependent on the successful development and commercialization of our late-stage product candidates, including mavacamten, TP-03 and NBTXR3.
- All of our product candidates are still in clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially adversely affected.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval of our product candidates in other jurisdictions.
- Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.
- If we breach our licenses or other intellectual property-related agreements for our product candidates or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.
- We rely on Perceptive Advisors (“Perceptive”), our founder and a significant shareholder in our company, as a source for identifying partners from which we may in-license product candidates. If Perceptive divests of its investment in our company or is no longer a significant shareholder, we may lose access to its expertise in sourcing opportunities and our business could be substantially harmed. Perceptive and its affiliates exercise significant influence over our Company, which may limit the ability of our investors and other holders to influence corporate matters and could delay or prevent a change in corporate control. As of December 1, 2021, Perceptive and its affiliates beneficially own 52.5% of our ordinary shares, based on the number of shares outstanding as of December 1, 2021. Two of our current non-employee directors are affiliated with Perceptive. We have also entered into a director nomination agreement (the “Director Nomination Agreement”) with Perceptive that provides Perceptive the right to designate nominees to our board of directors so long as Perceptive beneficially owns 5% or more of the total number of shares that it owns as of the completion of our initial public offering. Additionally, Perceptive may invest in or advise businesses that directly or indirectly compete with certain portions of our business or that are suppliers or customers of our business in such a way that may not always coincide with minority ADS holders’ interests.
- We rely on third parties to conduct some of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us, and our ability to successfully develop and commercialize any of our product candidates and technology may be adversely affected.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks investors should consider before making an investment in our securities, see “Risk Factors.”

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 109,015	$ 254,350
Prepaid expenses and other current assets	6,204	2,396
Other receivable	5,784	20,000
Total current assets	121,003	276,746
Restricted cash, non-current	20,000	—
Property and equipment, net	707	822
Operating lease right-of-use assets	206	1,706
Other non-current assets	10	12
Total assets	$ 141,926	$ 279,286
Liabilities, Redeemable Convertible Preferred Shares and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,639	$ 4,329
Accrued expenses	12,630	998
Current portion of operating lease liabilities	306	539
Withholding tax payable	5,957	—
Other current liabilities	1,727	360
Total current liabilities	22,259	6,226
Operating lease liabilities	—	1,341
Nonrefundable research deposit	20,000	20,000
Total liabilities	42,259	27,567
Commitments and contingencies (Note 7)		
Redeemable convertible preferred shares, $0.0001 par value. Authorized 11,024,178 and 10,971,231 shares as of September 30, 2021 and December 31, 2020, respectively; 11,024,178 and 10,971,231 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	352,729	349,789
Shareholders' deficit:		
Ordinary shares, $0.000017100448 par value. Authorized 2,859,432,812 shares as of September 30, 2021; 21,787,245 shares issued and outstanding at September 30, 2021; Authorized 2,859,742,435 shares as of December 31, 2020; 20,477,338 shares issued and outstanding at December 31, 2020	—	—
Additional paid-in capital	41,726	31,132
Accumulated other comprehensive income (loss)	64	(40)
Accumulated deficit	(339,040)	(163,935)
Total LianBio shareholders' deficit	(297,250)	(132,843)
Non-controlling interest	44,188	34,773
Total shareholders' deficit	(253,062)	(98,070)
Total liabilities, redeemable convertible preferred shares and shareholders' deficit	$ 141,926	$ 279,286

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, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Operating expenses:				
Research and development	$ 4,655	$ 116,915	$ 151,038	$ 118,173
General and administrative	8,889	2,129	22,496	7,492
Total operating expenses	13,544	119,044	173,534	125,665
Operating loss	(13,544)	(119,044)	(173,534)	(125,665)
Other income (expense):				
Interest income (expense), net	32	(1,293)	171	(1,280)
Other income (expense), net	3	99	(189)	81
Net loss before income taxes	(13,509)	(120,238)	(173,552)	(126,864)
Income (benefit) taxes	(397)	—	1,553	2
Net loss	(13,112)	(120,238)	(175,105)	(126,866)
Other comprehensive (loss) income:				
Foreign currency translation (loss) income, net of tax	(26)	(3)	104	(56)
Comprehensive loss	$ (13,138)	$ (120,241)	$ (175,001)	$ (126,922)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.63)	$ (11.71)	$ (8.52)	$ (12.36)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	20,690,908	10,265,811	20,549,310	10,265,811

See accompanying notes to the consolidated financial statements

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

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

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

	Redeemable Convertible Preferred Shares		Ordinary Shares		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total LianBio Shareholders' Deficit	Non-Controlling Interest	Total Shareholders' Deficit
	Shares	Amount	Shares	Amount						
Balance, December 31, 2019	5,500,000	$55,000	10,265,811	$ —	$ 8,516	$ —	$ (24,331)	$ (15,815)	$ 999	$ (14,816)
Share-based compensation expense	—	—	—	—	1,500	—	—	1,500	—	1,500
Net Loss	—	—	—	—	—	—	(4,114)	(4,114)	—	(4,114)
Comprehensive loss	—	—	—	—	—	(54)	—	(54)	—	(54)
Balance, March 31, 2020	5,500,000	$55,000	10,265,811	$ —	$ 10,016	$ (54)	$ (28,445)	$ (18,483)	$ 999	$ (17,484)
Share-based compensation expense	—	—	—	—	375	—	—	375	—	375
Beneficial conversion feature on issuance of convertible notes	—	—	—	—	2,439	—	—	2,439	—	2,439
Net Loss	—	—	—	—	—	—	(2,514)	(2,514)	—	(2,514)
Comprehensive Income	—	—	—	—	—	1	—	1	—	1
Balance, June 30, 2020	5,500,000	$55,000	10,265,811	$ —	$ 12,830	$ (53)	$ (30,959)	$ (18,182)	$ 999	$ (17,183)
Share-based compensation expense	—	—	—	—	383	—	—	383	—	383
Warrants issued in license agreement	—	—	—	—	—	—	—	—	33,774	33,774
Net Loss	—	—	—	—	—	—	(120,238)	(120,238)	—	(120,238)
Comprehensive Loss	—	—	—	—	—	(3)	—	(3)	—	(3)
Balance, September 30, 2020	5,500,000	$55,000	10,265,811	$ —	$ 13,213	$ (56)	$ (151,197)	$ (138,040)	$ 34,773	$ (103,267)

See accompanying notes to the consolidated financial statements

LianBio
Consolidated Statements of Cash Flows
(In thousands)

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net loss	$ (175,105)	$ (126,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash share consideration, issued in acquisition of IPR&D	9,415	33,774
Amortization of beneficial conversion feature	—	619
Non-cash operating lease expense (benefit)	(76)	108
Depreciation expense	278	30
Share based compensation expense	5,285	2,258
Unrealized foreign currency transaction (gain), net	(56)	(142)
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other current assets	(3,801)	(1,251)
Decrease in other receivable	14,216	—
Decrease (increase) in other non-current assets	2	(7)
(Decrease) increase in accounts payable	(2,690)	400
Increase in accrued expenses	11,568	3,409
Increase in amount due related to the MyoKardia license	—	33,281
Increase (decrease) in other current liabilities	1,434	(41)
Increase in withholding tax payable	5,957	—
Increase in related party payable	—	5,155
Net cash used in operating activities	(133,573)	(49,273)
Cash flows from investing activities:		
Purchase of property and equipment	(159)	(335)
Net cash used for investing activities	(159)	(335)
Cash flows from financing activities:		
Proceeds from exercise of share options	5,309	—
Proceeds from issuance of redeemable convertible preferred shares	3,000	—
Issuance costs related to redeemable convertible preferred shares	(60)	—
Issuance of convertible notes	—	15,000
Debt issuance costs related to convertible notes	—	(36)
Net cash provided by financing activities	8,249	14,964
Effect of exchange rate changes on cash and cash equivalents	148	(75)
Net decrease in cash, cash equivalents and restricted cash	$ (125,335)	$ (34,719)
Cash and cash equivalents, and restricted cash—beginning of period	254,350	$ 43,300
Cash and cash equivalents, and restricted cash—ending of period	$ 129,015	$ 8,581
Cash and cash equivalents—end of period	$ 109,015	$ 8,581
Restricted cash—end of period	$ 20,000	$ —
Cash and cash equivalents, and restricted cash—ending of period	$ 129,015	$ 8,581
Supplemental disclosure of non-cash financing and investing activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 247	$ 1,331
Issuance costs in accounts payable and other accrued liabilities	3,310	305
Beneficial conversion feature related to convertible notes	—	2,439

See accompanying notes to the consolidated financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Tabular Dollars in Thousands, Except Share and per Share Data)

(Unaudited)

1. Nature of Business

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

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

On November 3, 2021, the Company completed its initial public offering ("IPO") through an underwritten sale of 20,312,500 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 exercised their option to purchase an additional 593,616 ADSs at the initial public offering 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' options and aggregate net proceeds of $311.1 million after deducting underwriting discounts and commissions.

Concurrent with the IPO, all of the Company's convertible preferred shares then-outstanding (see Note 9) were automatically converted into an aggregate of 64,467,177 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 GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

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

The interim balance sheet as of September 30, 2021, and the interim consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred shares and shareholders' deficit for the three and nine months ended September 30, 2021 and 2020, and the cash flows for the nine months ended September 30, 2021 and 2020 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, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods or any future year or period.

(B) Use of Estimates

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

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

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

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents in deposits at financial institutions that exceed federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to material credit risk due to the financial position of the banking institutions. The Company has no off-balance sheet risk, 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 $339.0 million as of September 30, 2021 and $163.9 million as of December 31, 2020. The Company's cash and cash equivalents were $109.0 million and $254.4 million as of September 30, 2021 and December 31, 2020, respectively. The Company has financed its operations to date primarily through equity capital raises.

The Company believes that existing capital resources, including the net proceeds from the IPO in November 2021, 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) Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted average number of ordinary shares outstanding for the period. Diluted net loss per share excludes the potential impact of convertible preferred shares and unexercised warrants, because their effect would be anti-dilutive due to the Company's net loss. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per ordinary share are the same.

(D) Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates and manages its business as one reportable and operating segment, which is the business of license acquisitions, regulatory approvals, clinical trials, and commercial activity related to the current portfolio of in-licensed products. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance.

(E) Emerging Growth Company Status

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 issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to not avail itself of this exemption and, as a result, will adopt new or revised accounting standards on the relevant effective dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

(F) Fair Value of Financial Instruments

FASB guidance specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

a. Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

b. Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (e.g., quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies. The Company had no Level 2 assets or liabilities as of September 30, 2021 and December 31, 2020.

c. Level 3 – Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when the fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. The Company had no Level 3 assets or liabilities as of September 30, 2021 and December 31, 2020.

(G) Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents are carried at cost which approximates fair value due to their short-term nature. The Company maintains cash balances at both U.S.-based and foreign- based commercial banks.

Amounts included in restricted cash represent those required to be set aside by a contractual agreement with Pfizer, Inc. ("Pfizer"), and will remain restricted until such time as the upfront payment is utilized for specified in-licensing and co-development activities or until the agreement terminates.

A summary of cash, cash equivalents and restricted cash is as follows:

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 109,015	$ 254,350
Restricted cash, non-current	20,000	—
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 129,015	$ 254,350

(H) Property and Equipment

Property and equipment are stated at cost net of accumulated depreciation, which is computed by the straight-line method based on the estimated useful lives of the respective assets, as discussed below. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the leased assets. Maintenance and repair costs are charged to expense as incurred, and expenditures for major renewals and improvements are capitalized. The Company assesses the net book value of its property and equipment for impairment at least annually or when events or circumstances indicate that the carrying amounts may not be recoverable in the ordinary course of its business.

(I) Foreign Currency

The functional currencies of the Company's foreign subsidiaries primarily are the local currencies of the country in which the subsidiary operates. The Company's asset and liability accounts are translated using the current exchange rate as of the balance sheet date. Shareholders' deficit accounts are translated using historical rates at the balance sheet date. Revenue and expense accounts are translated using a weighted average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are accumulated as a separate component of shareholders' deficit within accumulated other comprehensive income (loss).

(J) Research and Development

Costs incurred for research and development are expensed as incurred. Included in research and development expense are personnel related costs, expenditures for laboratory equipment and consumables, payments made pursuant to licensing and acquisition agreements related to in-process research and development ("IPR&D"), and the cost of conducting clinical trials. Expenses incurred associated with conducting clinical trials include, but are not limited to, drug development trials and studies, drug manufacturing, laboratory supplies, external research, and payroll. Prepayments the Company makes for research and development services prior to services being rendered are recorded as prepaid expenses in the balance sheet and expensed as the services are provided.

(K) Acquisition of In-Process Research and Development

The Company has entered into agreements with third parties to acquire or license pharmaceutical product candidates for development. Such agreements generally require an initial payment by the Company when the contract is executed, and additional payments upon the achievement of certain milestones. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the pharmaceutical product candidate and achieves a certain sales volume. In accordance with FASB ASC Topic 730,

"Research and Development," expenditures for research and development, including upfront licensing fees and milestone payments associated with products that have not yet been approved by the NMPA, are charged to research and development expense as incurred as there is no alternative future use. Future contract milestone payments will be recognized as expense when achievement of the milestone is determined to be probable. Once a product candidate receives regulatory approval, subsequent license payments are recorded as an intangible asset and will be amortized over its estimated useful life.

(L) Accruals for Research and Development Expense and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to recognize its expense resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. This process involves reviewing open contracts and purchase orders, communicating with the applicable personnel to identify services that have been performed on behalf of the Company and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company records estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to the Company at that time. The Company's clinical trials accruals are dependent on the timely and accurate reporting of contract research organization and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. The Company periodically confirms the accuracy of its estimates with the service providers and records adjustments if necessary.

(M) Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, the amount of taxes currently payable or refundable is accrued, and deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax basis of existing assets and liabilities. Deferred tax assets also include realizable tax losses.

The deferred tax assets may be reduced by a valuation allowance, which is established when it is more likely than not that some portion or all of the deferred tax assets will not be realized. In addition, management is required to evaluate all available evidence, both positive and negative, when making its judgment to determine whether to record a valuation allowance for a portion, or all, of its deferred tax assets. Deferred tax assets and liabilities are measured using enacted income tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in income tax rate is recognized in the period that includes the enactment date.

The Company accounts for uncertainty in income taxes using a two-step approach. The first step requires the Company to conclude that a tax position, based solely on its technical merits, is more likely than not to be sustained upon examination by a tax authority. The second step requires the Company to measure the largest amount of benefit, determined on a cumulative probability basis, that is more likely than not to be realized upon ultimate settlement with tax authority. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Further, the benefit to be recorded in the consolidated financial statements is the amount most likely to be realized assuming a review by the tax authorities having all relevant information and applying current conventions. The Company's policy is to recognize interest and penalties related to income tax positions taken as a component of the provision for income taxes.

The Company does not anticipate any significant changes to its uncertain tax positions during the next 12 months. As of September 30, 2021, the Company was not aware of any anticipated audits by the IRS or any other state, local, or foreign taxing authorities for any other matters.

(N) Leases

In accordance with ASC 842, the Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of 12 months or less on its consolidated balance sheets and recognizes those lease payments in the income statement on a straight-line basis over the lease term. The Company's existing leases are for office space.

In addition to rent, leases may require the Company to pay additional costs, such as utilities, maintenance, and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components for its office leases. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as a right-of-use asset and liability. Rent expense for operating leases is recognized on a straight-line basis over the lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations and comprehensive loss.

(O) Share-Based Compensation

In June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Shared-Based Payment Accounting ("ASU 2018-07"), which supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payments arrangements related to the acquisition of goods and services from both employees and non-employees. The Company adopted ASU 2018-07 upon the formation of the Company on July 17, 2019. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant. Share compensation for shares granted to non-employees is determined as the fair value of the equity instruments issued. Compensation expense for non-employees is recognized in the same manner as if the Company has paid cash for the goods or services and therefore will be recognized immediately.

ASC 718 requires companies to measure the cost of employee services incurred in exchange for the award of equity instruments based on the estimated fair value of share-based award on the grant date. The share compensation awards issued to employees are equity classified, and the related expense is recognized over the requisite service period. The Company recognizes share-based award forfeitures only as they occur rather than an estimate by applying a forfeiture rate in accordance with ASU 2016-09.

The Company uses a Black-Scholes option-pricing model to value the Company's share option awards and the Monte Carlo simulation model to value the Company's performance share awards. The performance share awards vest upon meeting certain market conditions and service conditions. The share option awards generally vest pro-rata annually. Using these option-pricing models, the fair value of each share option award and performance share award is estimated on the grant date. The fair value of the share options and performance share awards is expensed on a straight-line basis over the vesting period. The expected volatility assumption used in both models is based on the volatility of the share price of comparable public companies. The expected life used in both models is determined using the "simplified method." The risk-free interest rate used in both models is based on the implied yield on a U.S. Treasury security at a constant maturity with a remaining term equal to the expected term of the option granted. The dividend yield used in both models is zero, as the Company has never declared a cash dividend.

(P) Deferred Offering Costs

Costs directly related to the Company's IPO were deferred for expense recognition. These deferred offering costs are temporarily capitalized and consist of legal fees, accounting fees, and other applicable professional services. As of September 30, 2021 and December 31, 2020, $4.5 million and $1.1 million of these deferred offering costs are reported on the accompanying balance sheets within "prepaid expenses and other current assets." With the completion of the Company's IPO on November 3, 2021, these deferred offering costs were concurrently reclassified to additional paid in capital.

(Q) Ordinary Share Split

On October 7, 2021, the Company's board of directors approved a 5.8478-for-1 forward share split, which was approved by the Company's shareholders on October 14, 2021. Effective as of October 14, 2021, the Company's issued and outstanding ordinary shares were impacted by the forward share split. All share and per share data in the consolidated financial statements and notes thereto have been retrospectively revised to reflect the forward share split. Ordinary shares underlying outstanding share options and other equity instruments and the respective exercise prices, if applicable, were proportionately adjusted in accordance with the terms of the appropriate securities agreements. The respective conversion prices related to ordinary shares reserved for issuance upon the conversion of the Company's convertible preferred shares were proportionately adjusted.

(R) Other Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements of fair value measurements. The Company adopted ASU 2018-13 effective January 1, 2020, and the adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 enhances and simplifies multiple aspects of the income tax accounting guidance in ASC 740. The standard will be effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years, with early adoption permitted. The guidance is generally effective as of January 1, 2021, with early adoption permitted. The Company adopted ASU 2019-12 in the first quarter of 2021 and the adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which introduces a new accounting model known as Credit Expected Credit Losses ("CECL"). CECL requires earlier recognition of credit losses on financial assets, while also providing additional transparency about credit risk. The Company adopted ASU 2016-13 in the third quarter of 2021 and applied the guidance prospectively. The adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

(S) Recently Issued Accounting Pronouncements Not Yet Adopted

The Company has evaluated recent accounting pronouncements through the date the financial statements were issued and filed with the SEC and believes that there are none that will have a material impact on the Company's consolidated financial statements.

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 amended September 2020, 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. Under the QED License Agreement, QED received a nonrefundable upfront payment of $10.0 million and was granted warrants to purchase 100,000 ordinary shares in Lian Oncology, a subsidiary of LianBio, valued at $1.0 million. Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model. The warrants were issued in three tranches with the aggregate number of shares across all tranches equaling 10% of the fully diluted equity of Lian Oncology as of the issue date. Vesting of the warrant shares are linked to regulatory milestones and the warrants expire 10 years from the issue date. The amended and restated option agreement also provides QED with the option to choose to either convert the warrant ("Subsidiary Warrant") into ordinary shares of the Company ("Parent Company Shares") or a warrant to purchase a certain number of Parent Company Shares ("Parent Company Warrant") immediately prior to an IPO of the Company. In the event QED chooses to convert the Subsidiary Warrant into Parent Company Shares, the number of Parent Company Shares QED is entitled to receive would be calculated as the aggregate fair market value of the ordinary shares of Lian Oncology that are under the Subsidiary Warrant, divided by the per share fair market value of the Parent Company Shares, on a fully diluted and as-converted basis and as of the date the Company sent QED the notice of the IPO. QED was entitled to choose to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant 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 were irrevocably terminated. The QED License Agreement also required the Company to refund QED for costs incurred on the study through the execution date which was determined to be $2.8 million and was recorded as a related party payable as of December 31, 2019 on the consolidated balance sheet. Additionally, QED is entitled to receive from the Company development milestone payments of up to $45.0 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 low- to mid-teens on the net sales of the licensed products, or (b) the applicable rate payable under QED's agreement with its upstream licensor (capped in the mid-teens).

License Agreement with MyoKardia

In August 2020, the Company entered into an exclusive license agreement (the "MyoKardia License Agreement") with MyoKardia Inc. ("MyoKardia," now a wholly-owned subsidiary of Bristol-Myers Squibb"), 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 exercisable into 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 9. The warrants, representing 17% of the fully diluted equity of Lian Cardiovascular, are exercisable by MyoKardia at any time after issuance. The amended and restated option agreement also provides MyoKardia with the option to choose to either convert the warrant ("Subsidiary Warrant") into ordinary shares of the Company ("Parent Company Shares") or a warrant to purchase a certain number of Parent Company Shares ("Parent Company Warrant") immediately prior to an IPO of the Company. MyoKardia was entitled to choose to convert the Subsidiary Warrant into Parent Company Shares, 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. MyoKardia was entitled to choose to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant MyoKardia was entitled to receive would be calculated as the aggregate intrinsic value of the Subsidiary Warrant (the number of the ordinary shares of Lian Cardiovascular under the Subsidiary Warrant multiplied by the difference between the strike price of the Subsidiary Warrant and the per share fair market value of Lian Cardiovascular), divided by the per share intrinsic value of the Parent Company Warrant (the difference between the strike price of the Parent Company Warrant and the per share fair market value of Parent Company Shares), on a fully diluted and as-converted basis on the date of the warrant conversion. This conversion feature was not required to be bifurcated as it is clearly and closely related to the equity host instrument, pursuant to ASC 815. As of October 12, 2021, MyoKardia elected not to exercise this option and, therefore, continues to hold its warrant to purchase 170,000 ordinary shares in Lian Cardiovascular. MyoKardia's option to convert the warrant irrevocably terminated upon the completion of the Company's IPO. Additionally, MyoKardia was entitled to receive a nonrefundable financing milestone payment of $35.0 million upon a specified financing event, which occurred on October 29, 2020. The financing milestone was recorded at present value upon execution of the MyoKardia License Agreement, with total imputed interest of $2.3 million accreted under the effective interest method through the date the liability was settled. The financing milestone was paid to MyoKardia in December 2020 as a result of the Series A Preferred financing. Additionally, MyoKardia is entitled to receive from the Company development milestone payments of up to $60.0 million upon achievement of specified development milestones, and sales milestone payments of up to $87.5 million based on cumulative net sales of mavacamten, plus tiered royalties on net sales ranging from the low to upper-teens.

Navire License

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. As of September 30, 2021, the Company had recorded and paid the first development milestone of $8.5 million for IND acceptance in the PRC.

Pfizer Strategic Collaboration

In November 2020, the Company entered into a strategic collaboration agreement (the "Pfizer Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which Pfizer will contribute up to $70.0 million of restricted, non-dilutive capital (the "Funds"), including a $20.0 million upfront payment, toward the Company's in-licensing and co-development activities in Greater China. The Company has accounted for the Pfizer Agreement as a contract to perform research and development services for others under ASC 730-20 and the consideration received for performing these services will be recognized as contra-R&D in the consolidated statement of operations as the services are performed. Additionally, as the upfront payment of the $20.0 million was received subsequent to December 31, 2020, the Company recognized a receivable for this amount on the consolidated balance sheet as of December 31, 2020. Upon receipt in 2021, the upfront payment was recorded as restricted cash within consolidated balance sheet and will remain restricted until such time as the upfront payment is utilized for specified in-licensing and co-development activities or until the Pfizer Agreement terminates. Under the Pfizer Agreement, Pfizer and LianBio will form a joint collaboration committee to discuss potential third party in-license opportunities and development and commercialization of the Company's products in Greater China. In the event the Company seeks to engage a third-party commercialization partner with respect to the commercialization of the Company's future products in Greater China, Pfizer will have a right to opt into such product. Upon opting in, a portion of the Funds will be used to pay for development and commercialization costs of such product and Pfizer will thereafter have a right of first negotiation and right of last refusal to obtain the commercialization rights of such product in Greater China, in each instance for additional, separate financial consideration. During the collaboration, Pfizer may provide in-kind support to us for marketing, development, and regulatory activities.

ReViral License

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

Tarsus License

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 ("DB") and Meibomian Gland Disease ("MGD") 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 exercisable into 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 9. 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 is 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. Accordingly, 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 such issuances, the Tarsus Warrants were irrevocably terminated. 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 2021, the Company was notified that Tarsus had dosed the first patient in the Saturn-2 Clinical Trial and achievement of the primary endpoint of the Saturn-1 Clinical Trial. The following milestones resulted in payments of $20.0 million being paid to Tarsus during the nine months ended September 30, 2021.

Landos License

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 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.

Nanobiotix License

In May 2021, the Company entered into an exclusive license agreement (the "Nanobiotix License Agreement") with Nanobiotix S.A. ("Nanobiotix"). Pursuant to the license agreement, Nanobiotix granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop and commercialize NBTXR3, a potential first-in-class radioenhancer in Mainland China, Hong Kong, Taiwan, and 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.

Lyra License

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 ("CRS") in Mainland China, Hong Kong, Taiwan, and 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.

4. Property and Equipment, Net

Property and equipment consisted of the following:

	September 30, 2021	December 31, 2020
Leasehold improvements	$ 697	$ 693
Furniture and fixtures	7	7
Computer equipment and software	283	180
Construction in progress	70	18
	1,057	898
Accumulated depreciation	(350)	(76)
Total property and equipment, net	$ 707	$ 822

Total depreciation related to property and equipment for the three and nine months ended September 30, 2021 and 2020 was $134.0 thousand, $271.0 thousand, $27.0 thousand, and $28.0 thousand, respectively.

5. Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	September 30, 2021	December 31, 2020
Advance payments to suppliers and rent deposit	$ 816	$ 1,070
Prepaid insurance	99	74
Deferred costs	4,545	970
VAT receivable	621	261
Other prepaid expenses	123	21
Total prepaid expenses and other current assets	$ 6,204	$ 2,396

6. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2021	December 31, 2020
Employee compensation and related benefits	$ 2,705	$ 236
Professional fees	5,417	683
Consulting and contracted research	4,484	49
Other	24	30
Total accrued expenses	$ 12,630	$ 998

7. 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, 2021 and December 31, 2020, 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.

8. 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.

The stated maximum availability of ordinary shares under the 2019 Plan is 12.0 million shares. Through September 30, 2021, there were awards issued for 9.7 million ordinary shares under this plan.

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 stated maximum availability of ordinary shares under the 2021 Equity Plan is 14.2 million shares.

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. The share options generally have a vesting period of four years.

In January 2020, the Company issued options to purchase 2,999,920 ordinary shares to senior management at an exercise price of $1.71 per share. During December 2020, the Company issued options to purchase an aggregate of 5,374,114 ordinary shares to employees, senior management and non-employee directors at an exercise price of $6.49 per share.

During the nine months ended September 30, 2021, the Company issued 5,758,787 options to purchase ordinary shares to senior management at exercise prices ranging from $6.49 to $6.90.

During the nine months ended September 30, 2020, the Company issued 2,999,920 options to purchase ordinary shares to senior management at an exercise price of $1.71.

A summary of share option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Terms in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2020	8,374,034	$ 4.78	9.62	$ 14,323
Granted	3,820,173	$ 6.84	—	—
Exercised	(1,309,907)	$ 4.06	—	—
Expired or forfeited	(3,075,938)	$ 5.97	—	—
Outstanding at September 30, 2021	7,808,362	$ 5.44	9.14	$ 60,544
Vested or expected to vest at September 30, 2021	1,528,222	$ 2.33	8.38	$ 16,612
Exercisable at September 30, 2021	1,528,222	$ 2.33	8.38	$ 16,612

As of September 30, 2021, $18.1 million of total unrecognized expense relates to non-vested share options is expected to be recognized over a weighted average period of 3.36 years from the date of grant. Options granted to senior management and employees generally vest in equal annual increments over four years.

Performance Share Awards

In May 2021, the Company granted certain option awards with both market-vesting conditions and service-vesting conditions to a member of management. The market condition is based on the Company's enterprise value. Per the terms of the award, these options will vest in two equal tranches based on the following thresholds:

1. 25% of the performance options shall vest upon the satisfaction of the Company achieving an enterprise value of not less than $2.0 billion at any time after the grant date in accordance with the service condition described below.

2. 25% of the performance options shall vest upon the satisfaction of the Company achieving an enterprise value of not less than $4.0 billion at any time after the grant date in accordance with the service condition described below.

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

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

A summary of the activity associated with these awards is as follows:

	Number of Options	Weighted Average Exercise Price	Average Remaining Term of Options (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	—	—	—	—
Granted	1,938,615	$ 6.90	9.88	—
Vested				
Exercised	—	—	—	—
Expired of forfeited	—	—	—	—
Outstanding at September 30, 2021	1,938,615	$ 6.90	9.88	—
Non-vested share units as of September 30, 2021	1,938,615	$ 6.90	9.88	—

The Company used a Monte-Carlo simulation to determine the grant date fair value for these awards, which takes into consideration the possible outcomes pertaining to the enterprise value market condition. The assumptions used in the Monte-Carlo simulation for the performance share units along with the weighted-average grant date fair value for awards granted in the periods presented are as follows:

Expected volatility	47.07%—80.64%
Dividend Yield	0%
Risk-free interest rate	0.81%—1.63%
Expected term, in years	4.87—10.00
Weighted average grant date fair value per share	$4.72

As of September 30, 2021, there was $8.3 million of total unrecognized of compensation cost related to the performance share units.

9. Equity

Ordinary Shares

As of September 30, 2021, the Company was authorized to issue up to 2,923,900,005 shares, of which 2,859,432,812 were authorized as ordinary shares with a par value of $0.000017100448, 5,500,000 were authorized Series Seed Preferred Shares with a par value of $0.0001, and 5,524,178 were authorized Series A Preferred Shares with a par value of $0.0001.

As of December 31, 2020, the Company was authorized to issue up to 2,923,900,005 shares, of which 2,859,742,435 were authorized as ordinary shares with a par value of $0.000017100448, 5,500,000 were authorized Series Seed Preferred Shares with a par value of $0.0001, and 5,471,231 were authorized Series A Preferred Shares with a par value of $0.0001.

Preferred Shares

The authorized, issued and outstanding shares, issue price, conversion price, liquidation preference and carrying value of the Company's redeemable convertible preferred shares as of the dates indicated were as follows (in thousands, except for share and per share data):

	September 30, 2021					
	Shares Authorized	Shares Issued and Outstanding	Issue Price	Per Share Conversion Price	Liquidation Preference	Carrying Value
Series Seed	5,500,000	5,500,000	$10.00	$ 1.72	$ 55,000	$ 55,000
Series A	5,524,178	5,524,178	$56.66	$ 9.69	297,729	297,729
					$ 352,729	$352,729

	December 31, 2020					
	Shares Authorized	Shares Issued and Outstanding	Issue Price	Per Share Conversion Price	Liquidation Preference	Carrying Value
Series Seed	5,500,000	5,500,000	$10.00	$ 1.72	$ 55,000	$ 55,000
Series A	5,471,231	5,471,231	$56.66	$ 9.69	294,789	294,789
					$349,789	$349,789

The Company's redeemable convertible preferred shares are not liability classified as they do not embody an unconditional obligation requiring the issuer to redeem the instrument by transferring its assets at a specified date or an event certain to occur. Due to the conversion at the option of the holder and redemption upon an occurrence that is not solely within the Company's control, the Company classified the redeemable convertible preferred shares in mezzanine equity rather than as a component of shareholders' deficit.

The characteristics of the redeemable convertible preferred shares are as follows:

Voting

The holders of the redeemable convertible preferred shares have one vote for each ordinary share into which the shares of redeemable convertible shares may be converted, subject to certain limitations.

Dividends

The holders of redeemable convertible preferred shares are entitled to receive non-cumulative dividend preference over the ordinary shareholders only when and if declared by the Board of Directors. As of September 30, 2021 and December 31, 2020, no dividends have been declared or paid.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company, the holders of the then outstanding redeemable convertible preferred shares will have distribution preference over the ordinary shareholders in the amount of 100% of their original purchase price plus accrued but unpaid dividends. If the assets and funds to be distributed among the holders of redeemable convertible preferred shares are insufficient to permit the full payment to which the holders are entitled, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of redeemable convertible preferred shares in proportion to the preferential amount each such holder is otherwise entitled to receive before distribution is made to the ordinary shareholders.

Conversion

The Series Seed Preferred Shares are convertible, at the option of the holder, into such number of fully paid shares of the Company's ordinary shares as is determined by dividing the original issuance price by the conversion price in effect at the time of conversion. Based on the conversion ratios in effect as of September 30, 2021 and December 31, 2020, after giving effect to the 5.8478-for-1 share split effected October 14, 2021, the Series Seed Preferred Shares converted into an aggregate of 32,162,900 of the Company's ordinary shares on November 3, 2021.

Based on the conversion ratios in effect as of September 30, 2021 and December 31, 2020, after giving effect to the 5.8478-for-1 share split effected October 14, 2021, the Series A Preferred Shares converted into an aggregate of 32,304,277 of the Company's ordinary shares on November 3, 2021.

Redemption

No redeemable convertible preferred shares are unilaterally redeemable by either the shareholders or the Company.

Warrants

In August 2020, the Company issued a warrant exercisable into 170,000 ordinary shares of Lian Cardiovascular. The warrants are equity classified and were issued by Lian Cardiovascular, a wholly owned subsidiary of the Company, as partial consideration to MyoKardia for the MyoKardia License Agreement. The warrants, if exercised, represent 17% of the fully diluted equity of Lian Cardiovascular. The warrants are accounted for under ASC 718 Compensation – Stock Compensation and are fair valued on the grant date using the Black- Scholes Model based on the following weighted average assumptions:

Current Price of the Underlying Share	$ 275.00
Exercise Price	$ 275.00
Expected Term	10 years
Risk Free Interest Rate	0.60%
Dividend Yield	0%
Expected Volatility	70%

In March 2021, the Company issued three warrants exercisable into 125,000 ordinary shares of Lian Ophthalmology. The warrants are equity classified and were issued by Lian Ophthalmology, a wholly owned subsidiary of the Company, as partial consideration to Tarsus for the Tarsus License Agreement. The warrants, if exercised, represent 12.5% of the fully diluted equity of Lian Ophthalmology. The warrants are accounted for under ASC 718 Compensation – Stock Compensation and are fair valued on the grant date using the Black-Scholes Model based on the following weighted average assumptions:

Current Price of the Underlying Share	$ 109.00
Exercise Price	$ 109.00
Expected Term	10 years
Risk Free Interest Rate	1.70%
Dividend Yield	0%
Expected Volatility	62.50%

Non-controlling Interest

The equity classified warrants issued at the subsidiary level allow the holder to purchase ordinary shares of the Company's respective wholly owned subsidiaries, thus creating a non-controlling interest. The Company recorded the fair value of the warrants as non-controlling interest in the equity section of the balance sheet. As the warrants are unexercised as of September 30, 2021 and December 31, 2020, no earnings were attributed to the non-controlling interest.

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, 2021 and 2020 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, 2021	Three Months Ended September, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Numerator				
Net Loss attributable to ordinary shareholders	$ (13,112)	$ (120,238)	$ (175,105)	$ (126,866)
Denominator				
Weighted-average shares – basic and diluted	20,690,908	10,265,811	20,549,310	10,265,811
Net loss per ordinary share – basic and diluted	$ (0.63)	$ (11.71)	$ (8.52)	$ (12.36)

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.

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Redeemable Convertible Preferred Shares	11,024,178	5,500,000	11,024,178	5,500,000
Convertible Notes	—	10,211,527	—	10,211,527
Employee Share Options	9,746,977	2,999,920	9,746,977	2,999,920
Warrants in Lian Oncology issued to QED	100,000	100,000	100,000	100,000
Warrants in Lian Cardiovascular issued to MyoKardia	170,000	170,000	170,000	170,000
Warrants in Lian Ophthalmology issued to Tarsus	125,000	—	125,000	—

10. Convertible Notes

In June 2020, the Company issued $15.0 million aggregate principal non-interest bearing convertible promissory notes due June 29, 2021 (the "2020 Convertible Notes") to Perceptive. The 2020 Convertible Notes become convertible into the Company's ordinary shares at a conversion price of $1.47, at the option of the holder, upon the occurrence of the next preferred equity financing.

The fair value of the Company's ordinary shares as of the issuance date was $1.71 per share compared to the conversion rate of $1.47 per share and therefore the 2020 Convertible Notes contain a beneficial conversion feature ("BCF"). The Company measured the BCF at $2.4 million as the intrinsic value of the conversion option at the commitment date, representing the difference between the conversion price and the Company's share price on the commitment date. The BCF was recorded in additional paid-in capital as a discount to the carrying value of the 2020 Convertible Notes and amortized to interest expense using the effective interest method.

In October 2020, as part of the Series A preferred issuance, the 2020 Convertible Notes were subsequently converted into 10,211,527 ordinary shares, in accordance with their terms and at their conversion price of $1.47 per share, and following such conversion, the 2020 Convertible Notes were cancelled.

The Company accounted for the conversion of the 2020 Convertible Notes as interest expense of $1.6 million within interest expense in the consolidated statement of operations and comprehensive loss as of the year ended December 31, 2020. The interest expense upon conversion was calculated as the difference between (i) the 2020 Convertible Note principal amount of $15.0 million and (ii) the carrying value of the 2020 Convertible Notes, including the principal balance of the 2020 Convertible Notes of $13.4 million.

The Company recognized interest expense of $0.6 million related to the BCF during the three and nine months ended September 30, 2020, in connection with the 2020 Convertible Notes.

11. Subsequent Events

Initial Public Offering

On November 3, 2021, the Company completed its initial public offering ("IPO") through an underwritten sale of 20,312,500 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 exercised their option to purchase 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 $311.1 million after deducting underwriting discounts and commissions.

Concurrent with the IPO, all of the Company's convertible preferred shares then-outstanding were automatically converted into an aggregate of 64,467,177 ordinary shares and were reclassified into permanent equity. Following the IPO, there were no preferred shares outstanding.

On October 5, 2021, QED exercised their option to convert certain warrants that had been granted to them as partial consideration for the grant of certain licenses and rights to the Company pursuant to the license agreement entered into with them (the "QED Warrants"). Accordingly, on October 18, 2021, the Company issued to QED a warrant to purchase 347,569 of the Company's ordinary shares at an exercise price of $0.000017100448 per share and, concurrently with such issuance, the QED Warrants were deemed to be performed and settled in full and were irrevocably terminated.

On October 12, 2021, MyoKardia elected not to exercise their option to convert their warrant that had been granted to them as partial consideration for the grant of exclusive licenses and rights to the Company pursuant to the license agreement entered into with them (the "Subsidiary Warrant"). MyoKardia's option to convert the warrant irrevocably terminated upon the completion of the Company's IPO.

In March 2021, the Company granted three warrants (collectively, the "Tarsus Warrants") to Tarsus as partial consideration for the grant of certain licenses and rights to the Company pursuant to our development and license agreement with Tarsus (the "Tarsus Agreement"). On October 18, 2021, Tarsus exercised its options to convert the Tarsus Warrants under the Tarsus Option Agreement. Accordingly, the Company subsequently issued to Tarsus 78,373 of the Company's ordinary shares and two warrants to purchase an aggregate of 156,746 of the Company's ordinary shares at an exercise price of $0.000017100448 per share. Following such issuances, the Tarsus Warrants were deemed to be performed and settled in full and were irrevocably terminated.

Share Split

On October 7, 2021, the Company's board of directors approved a 5.8478-for-1 forward share split, which was approved by the Company's shareholders on October 14, 2021. Effective on October 14, 2021, the Company's issued and outstanding ordinary shares were impacted by the forward share split. All share and per share data in the consolidated financial statements and notes thereto have been retroactively revised to reflect the forward share split. Ordinary shares underlying outstanding share options and other equity instruments and the respective exercise prices, if applicable, were proportionately adjusted in accordance with the terms of the appropriate securities agreements. The respective conversion prices related to ordinary shares reserved for issuance upon the conversion of the Company's convertible preferred shares were proportionately adjusted.

Lease Agreement

On November 4, 2021, the Company entered into a real estate lease for office space in Shanghai, effective November 16, 2021. The initial lease term ends on March 31, 2025 with an option to renew for one additional period of 36 months. The Company shall pay a total of approximately $4.9 million in base rent plus management fees over the initial term of the lease. Additionally, the Company shall pay certain other monthly and non-recurring fees and amounts as specified in the lease.

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 financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our final prospectus (the "IPO Prospectus") dated October 31, 2021 and filed with the Securities and Exchange Commission (the "SEC") on November 2, 2021, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act"). This discussion, particularly information with respect to our future results of operations or financial condition, business strategy, and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Cautionary Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q. Investors should review the disclosure under the heading "Risk Factors" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

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

Recent Business Highlights and Clinical Development Updates

Initial Public Offering

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 close of the IPO, on December 1, 2021, the underwriters exercised their option to purchase 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 $311.1 million after deducting underwriting discounts and commissions.

Mavacamten

In November 2021, we initiated and completed enrollment and dosing in a pharmacokinetic ("PK") study of mavacamten in healthy volunteers. We expect to begin treating patients in the Phase 3 EXPLORER-China ("EXPLORER-CN") trial of mavacamten in obstructive hypertrophic cardiomyopathy ("oHCM") in the first quarter of 2022.

In November 2021, our partner Bristol-Myers Squibb ("BMS") announced that the U.S. Food and Drug Administration ("FDA") has extended the review of the U.S. New Drug Application ("NDA") for mavacamten for the treatment of patients with symptomatic oHCM to April 28, 2022 to allow sufficient time to review information pertaining to updates to BMS's proposed Risk Evaluation Mitigation Strategy ("REMS"). We do not anticipate this review extension to impact the timing of our planned clinical development strategy to support the registration of mavacamten in Mainland China.

In November 2021, BMS presented data at the American Heart Association Scientific Sessions 2021 from the Phase 2 MAVERICK study demonstrating long-term efficacy and safety of mavacamten in patients with non-obstructive hypertrophic cardiomyopathy.

Infigratinib

In August 2021, we announced that we began treating patients in a Phase 2a clinical trial of infigratinib in locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 ("FGFR2") gene amplification and other advanced solid tumors with FGFR genomic alterations.

TP-03

In November 2021, our partner Tarsus Pharmaceuticals, Inc. ("Tarsus") presented data from two studies on the prevalence and impact of Demodex blepharitis ("DB") at the American Academy of Optometry 2021 Annual Meeting. Data from the Titan real-world prevalence study demonstrated that DB accounts for 69% of all blepharitis cases and that current management tools for this disease are largely ineffective. Data from the multi-center observational Atlas impact study demonstrated that DB is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in 80% of patients.

NBTXR3

In October 2021, our partner Nanobiotix S.A. ("Nanobiotix") presented data at the 2021 Annual Meeting of the American Society for Radiation Oncology. The first analysis of overall survival ("OS") and progression-free survival ("PFS") from the ongoing Phase 1 trial of NBTXR3 in elderly and frail locally advanced head and neck squamous cell carcinoma patients ineligible for cisplatin and intolerant to cetuximab (Study 102) demonstrated median OS of 18.1 months and median PFS of 10.6 months in the evaluable population (n=41) from the dose expansion part of the study. NBTXR3 administration was feasible and well-tolerated overall. A total of 8 Grade 3-4 NBTXR3-related adverse events ("AEs") were observed in 8 patients. Of these AEs related to NBTXR3, 5 serious adverse events ("SAEs") were observed including dysphagia, sepsis, soft tissue necrosis, stomatitis, and tumor hemorrhage. Of the SAEs, one death from sepsis assessed by the investigator as possibly related to NBTXR3, radiotherapy, and cancer was observed.

LYR-210

In October 2021, our partner Lyra Therapeutics, Inc. ("Lyra") presented new data from the Phase 2 LANTERN clinical trial of LYR-210 in surgically naïve chronic rhinosinusitis patients who had failed previous medical management at the 67th Annual Meeting of the American Rhinologic Society ("ARS"). The data presented at ARS demonstrated that 24 weeks after LYR-210 removal, 50% of treated patients continued to experience durable symptom improvement. LYR-210 continued to show strong safety during the 24-week follow up period with no increased incidence of treatment-related AEs.

Omilancor

In November 2021, our partner Landos Biopharma, Inc. ("Landos") announced that prior to initiating a pivotal Phase 3 study, the company plans to leverage the results of the prior Phase 2 study of omilancor in mild-to-moderate ulcerative colitis ("UC") patients to design and initiate a Phase 2b study in 2022. The Phase 2b study is expected to provide additional data to inform the pivotal Phase 3 study design. Accordingly, we are evaluating our clinical development strategy within our territories.

In October 2021, Landos presented positive translational data from the Phase 2 trial of omilancor in mild-to-moderate UC at United European Gastroenterology Week. Patients remaining on omilancor after the induction phase of the trial maintained low Mayo scores, an assessment of disease severity in UC, and nearly 90% of patients achieved remission thresholds in stool frequency and rectal bleeding after 36 weeks of open-label treatment.

Board of Director Appointments

In October 2021, we announced the appointments of Jesse Wu and Susan Silbermann to our Board of Directors. Mr. Wu is the former Chairman of Johnson & Johnson China. Ms. Silbermann is the former Global President, Emerging Markets at Pfizer.

Leadership Team Appointments

In August 2021, we announced the appointment of Pascal Qian as China General Manager. Mr. Qian is a member of our executive leadership team and is responsible for building out our China operations and commercial infrastructure.

In October 2021, we announced the appointment of Michael Humphries, MBBS, as Chief Scientific Advisor. Dr. Humphries is responsible for guiding our research and development ("R&D") strategy, advancing our pipeline and leading the assessment of new in-licensing opportunities.

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 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. Although we have not been materially impacted by the COVID-19 pandemic to date, other outbreaks may occur, or there could be further resurgences of the COVID-19 pandemic, which could cause business disruptions in the future.

Efforts to contain the spread of the COVID-19 pandemic in the United States (including in New Jersey, where our U.S. headquarters is located) have included quarantines, shelter-in-place orders and various other government restrictions in order to control the spread of this virus.

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

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

See "Risk Factors" included in this Quarterly Report on Form 10-Q for a further discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Key Components of Results of Operations

Revenue

To date, we have not generated any material revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future.

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 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 years indicated (in thousands):

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Research and development expenses:				
Licensing fees	$ —	$ 114,375	$ 136,915	$ 114,375
Employee related expense	1,921	780	5,031	1,632
CRO costs	1,952	376	6,521	672
Other costs	782	1,384	2,571	1,494
Total	$ 4,655	$ 116,915	$ 151,038	$ 118,173

The following table sets forth a breakdown of licensing fees by program for the years indicated (in thousands):

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Licensing fees:				
Mavacamten	$ —	$ 106,375	$ —	$ 106,375
BBP-398	—	8,000	8,500	8,000
Sisunatovir	—	—	14,000	—
TP-03	—	—	64,415	—
BT-11 and NX-13	—	—	18,000	—
NBTXR3	—	—	20,000	—
LYR-210	—	—	12,000	—
Total	$ —	$ 114,375	$ 136,915	$ 114,375

General and administrative expenses

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

We expect that our general and administrative expense 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.

Licensing arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are generally required to make upfront payments upon entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant product candidate under these agreements, as well as tiered royalties based on net sales of the license products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our consolidated financial statements and totaled $0.0 million, $136.9 million, $114.4 million, and $114.4 million for the three and nine months ended September 31, 2021 and 2020, respectively.

Interest (expense) income, net

Interest (expense) income, net consists of interest expense from the payment made upon reaching the financing milestone under the exclusive license agreement with MyoKardia (“the MyoKardia Agreement”), offset by interest income received on our cash balances.

Other income (expense), net

Other income (expense), net consists of unrealized gains on foreign currencies held in our China subsidiary, Shanghai LianBio Development Co., Ltd., offset by bank fees incurred on our cash balances.

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 recorded income tax (benefit) expense of ($0.4) million and $1.6 million for the three and nine months ended September 30, 2021 and income tax expense of $0.0 million and $0.0 million for the three and nine months ended September 30, 2020.

At December 31, 2020, we had net operating loss (“NOL”) carryforwards for federal income tax purposes of approximately $22.7 million, which do not expire. We had foreign NOL carryforwards of $1.4 million, which will expire if unused in 2025.

As required by Accounting Standards Codification (“ASC”) Topic 740, Income Taxes, our management has evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets, which are composed principally of NOL carryforwards, intangible assets, share compensation, and accrued expenses. Management has determined that it is more likely than not that we will not realize the benefits of the deferred tax assets. As a result, a valuation allowance of $43.1 million was recorded as of December 31, 2020. As of September 30, 2021, the valuation allowance decreased by approximately $1.2 million from December 31, 2020.

Cayman Islands

We are incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands.

People's Republic of China

Our subsidiaries incorporated in China are governed by the PRC Enterprise Income Tax Law ("EIT Law"), and regulations. Under EIT Law, the standard Enterprise Income Tax ("EIT") rate is 25.0% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years.

Hong Kong

Our subsidiaries incorporated and carrying on a trade or business in Hong Kong are generally subject to profits tax at a rate of 16.5%. Tax losses incurred may be carried forward indefinitely to offset any taxable profits in subsequent years. Hong Kong does not levy tax on capital gains or non-Hong Kong sourced income. Payments of dividend and interest are not subject to withholding tax in Hong Kong, however, certain payments (such as payment for right to use intellectual properties) made to non-resident persons may be subject to withholding tax.

Results of operations

Comparison of the three months ended September 30, 2021 and 2020

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

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020
Operating expenses (in thousands):		
Research and development	$ 4,655	$ 116,915
General and administrative	8,889	2,129
Total operating expenses	13,544	119,044
Operating loss	(13,544)	(119,044)
Other income (expense):		
Interest income (expense), net	32	(1,293)
Other income, net	3	99
Net loss before income taxes	(13,509)	(120,238)
Income tax (benefit)	(397)	—
Net loss	$ (13,112)	$ (120,238)

Research and development expenses

Research and development expenses decreased by $112.3 million from $116.9 million for the three months ended September 30, 2020 to $4.6 million for the three months ended September 30, 2021. For the three months ended September 30, 2021, research and development cost was primarily attributable to $1.9 million in personnel-related expenses and $2.1 million in development activities to support our clinical trials and professional fees.

For the three months ended September 30, 2020, research and development cost was primarily attributable to (i) $72.7 million in upfront and milestone payments and $33.8 million of expenses related to the warrant issued in connection with our exclusive license agreement with MyoKardia (the "MyoKardia Agreement") and (ii) the $8.0 million upfront payment for our exclusive license agreement with Navire (the "Navire Agreement").

General and administrative expenses

General and administrative expenses increased by $6.8 million from $2.1 million for the three months ended September 30, 2020 to $8.9 million for the three months ended September 30, 2021. The increase was primarily attributable to a $3.5 million increase in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and a $2.9 million increase, primarily attributable to legal service costs, consulting costs and accounting services.

Interest income (expense)

Interest income (expense) decreased by $1.3 million from ($1.3) million for the three months ended September 30, 2020 to $0.0 million for the three months ended September 30, 2021. The decrease was primarily attributable to interest expense in 2020 related to imputed interest related to the achievement of the financing milestone under the MyoKardia Agreement that did not exist in 2021 and $0.6 million interest expense for the three months ended September 30, 2020 related to the conversion in June 2020 of the $15.0 million convertible promissory notes due June 29, 2021 issued to Perceptive (the "2020 Convertible Notes").

Other income, net

Other income (expense), net decreased by $0.1 million from $0.1 million for the three months ended September 30, 2020 to $0.0 million for the three months ended September 30, 2021. The decrease was primarily attributable to unrealized loss on foreign currencies held in our China subsidiary and by bank fees incurred on our cash balances.

Income taxes

Our income benefit was $0.4 million, resulting in an effective income tax rate of 1.0% for the three months ended September 30, 2021 as compared to $0.0 million, or an effective income tax rate of 0.0%, for the same period in 2020. Our income tax benefit for the three months ended September 30, 2021 was primarily due to an increase in pretax losses.

Comparison of the Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Operating expenses (in thousands):		
Research and development	$ 151,038	$ 118,173
General and administrative	22,496	7,492
Total operating expenses	173,534	125,665
Operating loss	(173,534)	(125,665)
Other income (expense):		
Interest income (expense), net	171	(1,280)
Other (expense) income, net	(189)	81
Net loss before income taxes	(173,552)	(126,864)
Income taxes	1,553	2
Net loss	$ (175,105)	$ (126,866)

Research and development expenses

Research and development expenses increased by $32.9 million from $118.2 million for the nine months ended September 30, 2020 to $151.0 million for the nine months ended September 30, 2021. For the nine months ended September 30, 2021, research and development cost was primarily attributable to (i) $55.0 million upfront and development milestone payments and $9.4 million of expenses related to warrants issued in connection with our development and license agreement with Tarsus, (ii) a $20.0 million upfront payment pursuant to our license, development and commercialization agreement with Nanobiotix, (iii) a $18.0 million upfront payment pursuant to our license and collaboration agreement with Landos, (iv) a $14.0 million upfront payment pursuant to our co-development and license agreement with ReViral, (v) a $12.0 million upfront payment pursuant to our license and collaboration agreement with Lyra, and (vi) a $8.5 million development milestone payment pursuant to the Navire Agreement. The remaining increase was attributable to higher personnel-related expenses, including share-based compensation expense, as a result of increased employee headcount, and development activities to support our clinical trials and professional fees.

For the nine months ended September 30, 2020, research and development cost was primarily attributable to (i) $72.7 million in upfront and milestone payments and $33.8 million of expenses related to the warrant issued in connection with the MyoKardia Agreement and (ii) the $8.0 million upfront payment for the Navire Agreement.

General and administrative expenses

General and administrative expenses increased by $15.0 million from $7.5 million for the nine months ended September 30, 2020 to $22.5 million for the nine months ended September 30, 2021. The increase was primarily attributable to (i) $7.7 million increase in payroll and personnel-related expenses, including share-based compensation expense, and employee severance, as a result of changes to employee headcount, (ii) $2.9 million increase in consulting costs, and (iii) $2.3 million increase in legal service costs.

Interest income (expense, net)

Interest income (expense), net decreased by $1.4 million from ($1.3) million for the nine months ended September 30, 2020 to $0.1 million for the nine months ended September 30, 2021. The decrease was primarily attributable to interest expense in 2020 related to the imputed interest related to the achievement of the financing milestone under the MyoKardia Agreement that did not exist in 2021 as well as interest on the 2020 Convertible Note.

Other income (expense), net

Other income (expense), net decreased by ($0.3) million from $0.1 million for the nine months ended September 30, 2020 to ($0.2) million for the nine months ended September 30, 2021. The decrease was primarily attributable to unrealized loss on foreign currencies held in our China subsidiary and by bank fees incurred on our cash balances.

Income taxes

Our income tax expense was $1.6 million, resulting in an effective income tax rate of 0.9% for the nine months ended September 30, 2021 as compared to income tax expense of $0.0 million, or an effective income tax rate of 0.0%, for the same period in 2020. Our income tax expense for the nine months ended September 30, 2021 was primarily due to the effect of cash taxes associated with certain income that cannot be deferred for U.S. income tax purposes.

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 and the Series A financing, as well as the issuance of the 2020 Convertible Notes. As of September 30, 2021, we had cash and cash equivalents of $109.0 million.

On November 3, 2021, the Company completed its initial public offering ("IPO") through an underwritten sale of 20,312,500 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 exercised their option to purchase 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' options and aggregate net proceeds of $311.1 million after deducting underwriting discounts and commissions.

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. See "Risk Factors—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."

Funding requirements

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

To date, we have not generated any revenue. We do not expect to generate material product revenue 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;
- impact of the COVID-19 pandemic 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 (in thousands):

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net cash (used in) provided by:		
Operating activities	$ (133,573)	$ (49,273)
Investing activities	(159)	(335)
Financing activities	8,249	14,964

Net cash used in operating activities

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

During the nine months ended September 30, 2020, operating activities used approximately $49.3 million of cash, primarily due to our net loss of $126.9 million, partially offset by non-cash items of $33.8 million related to the warrant granted to MyoKardia, $33.2 million related to the MyoKardia sellers' financing and $2.3 million related to share-based compensation expense, as well as other changes related to operating assets and liabilities.

Net cash used in investing activities

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

During the nine months ended September 30, 2020, investing activities used approximately $0.3 million, primarily resulting from the purchases of property and equipment.

Net cash provided by financing activities

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

During the nine months ended September 30, 2020, financing activities provided approximately $15.0 million in net proceeds, primarily resulting from the net proceeds from the 2020 Convertible Notes.

Contractual obligations

The following table presents our contractual obligations at September 30, 2021 (in thousands):

	Payments Due by Period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
	(in thousands)				
Operating lease obligations(1)	$ 331	$—	$—	$ —	$331

(1) The operating lease obligations are related to the facility lease for our China headquarters in Shanghai expiring in March 2022 and our Princeton, New Jersey lease expiring in October 2021. During the three months ended September 30, 2021, we reduced the term in our Shanghai lease, thus resulting in a remeasurement of the previous right of use asset and liability.

We also have obligations to fund clinical trial commitments under the QED License over the remaining term of the QED License.

Off-balance sheet arrangements

In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical accounting policies and significant judgments and estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates are different assumptions and conditions. For a discussion of our critical accounting estimates, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the IPO Prospectus, the notes to our audited financial statements appearing in the IPO Prospectus and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. There have been no material changes to the Company’s critical accounting policies and estimates through September 30, 2021 from those discussed in the IPO Prospectus.

Recently issued accounting standards

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows are disclosed in the footnote to which each relates within the financial statements included in this Quarterly Report on Form 10-Q.

Qualitative & quantitative disclosures about market risk

We are exposed to market risk including foreign exchange risk, credit risk and cash flow interest rate risk.

Foreign currency exchange rate risk

Our business mainly operates in China with transactions in renminbi, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risk should be limited, the value of any investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the renminbi because a portion of the value of our business is effectively denominated in renminbi, while the ADSs will be traded in U.S. dollars.

Renminbi is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China ("PBOC"), controls the conversion of renminbi into foreign currencies. The value of renminbi is subject to changes in the central government policies and to international economic and political developments affect supply and demand in the China Foreign Exchange Trading System market.

Translation of the net proceeds that we received from our initial public offering into renminbi will also expose us to currency risk. The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affect by, among other things, changes in China's political and economic conditions. To the extent that we need to convert U.S. dollars into renminbi for our operations or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into renminbi, appreciation of the renminbi against the U.S. dollar would have an adverse effect on the renminbi amount we receive from the conversion. Conversely, if we decide to convert renminbi to U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the renminbi would have a negative effect on the U.S. dollar amounts available to us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief 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 Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2021, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this Form 10-Q was (a) reported within the time periods specified by SEC rules and regulations, and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of 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-OTHER INFORMATION

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.

RISK FACTORS

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. Investors should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Doing Business in China and Our International Operations

Changes in the political and economic policies of the Chinese government or in relations between China and the United States may materially and adversely affect our business, financial condition, results of operations and the market price of our ADSs.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations. In July 2021, the Chinese government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities ("VIEs"). In light of such developments, the SEC has imposed enhanced disclosure requirements on China-based companies. Although we do not have a VIE structure, due to our extensive operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with extensive operations in China could adversely affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate, the Chinese government may intervene with our operations and our business in China and the United States, and the market price of our ADSs may also be adversely affected.

The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs.

The Chinese government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to further regulatory, political and societal goals. The Chinese government has recently published new policies that significantly affected certain industries such as the education and internet industries, and we cannot rule out the possibility that it will in the future release regulations or policies regarding our industry that could require us to seek permission from Chinese authorities to continue to operate our business, which may adversely affect our business, financial condition and results of operations. Furthermore, recent statements made by the Chinese government have indicated an intent to increase the government's oversight and control over offerings of companies with significant operations in China that are to be conducted in foreign markets, as well as foreign investment in China-based issuers like us. Any such action, once taken by the Chinese government, could significantly limit or completely hinder our ability to continue to offer ADSs to our investors, and could cause the value of our ADSs to significantly decline or become worthless.

Changes in U.S. and Chinese regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ADSs.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to China, our industry or on us. We conduct clinical activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of raw materials in relation to drug development, our ability to raise capital, the market price of our ADSs or prevent us from selling our drug products in certain countries. Furthermore, the SEC has issued statements primarily focused on companies with significant China-based operations, such as us. For example, on July 30, 2021, Gary Gensler, Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which Chairman Gensler stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with significant China-based operations. The statement also addressed risks inherent in companies with VIE structures. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations in China. However, it is possible that this Quarterly Report on Form 10-Q and the Company's other filings with the SEC may be subject to enhanced review by the SEC, and that this additional scrutiny could affect our ability to effectively raise capital in the United States.

In response to the SEC's July 30, 2021 statement, the CSRC announced on August 1, 2021, that "[i]t is our belief that Chinese and U.S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of China-based companies listed in the U.S. so as to form stable policy expectations and create benign rules framework for the market." While the CSRC will continue to collaborate "closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures," it emphasized that it "has always been open to companies' choices to list their securities on international or domestic markets in compliance with relevant laws and regulations."

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated, if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension or if the Chinese government exerts more oversight and control over securities offerings that are conducted in the United States, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ADSs.

Compliance with China's Data Security Law, Cybersecurity Review Measures (revised draft for public consultation), Personal Information Protection Law, regulations and guidelines relating to the multi-level protection scheme and any other future laws and regulations may entail significant expenses and could materially affect our business.

China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. 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. With China's growing emphasis of its sovereignty over data derived from China, the outbound transmission of de-identified or pseudonymized health data for clinical trials may be subject to the new national security legal regime, including the Data Security Law, the Cyber Security Law of the People's Republic of China (the "Cyber Security Law"), the Personal Information Protection Law ("PIPL"), and various implementing regulations and standards. 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, 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.

China's Data Security Law took effect in September 2021. The Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. The classification of data is based on its importance in economic and social development, as well as the degree of harm expected to be caused to national security, public interests, or legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used. The security assessment mechanism was also included in the PIPL, which was promulgated in August 2021 and became effective on November 1, 2021, for the Chinese government to supervise certain cross-border transfers of personal information.

Additionally, 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 China adopt a multi-level protection scheme ("MLPS"), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data 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.

Recently, the Cyberspace Administration of China 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, the Cyber Security Law and the Measures on Cybersecurity Review, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests." On July 10, 2021, the Cyberspace Administration of China published a revised draft of the Cybersecurity Review Measures, expanding the cybersecurity review to data processing operators in possession of personal information of over 1 million users if the operators intend to list their securities in a foreign country.

It is 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. China's regulators may impose penalties for non-compliance ranging from fines or suspension of operations, and this could lead to us delisting from the U.S. stock market.

Also, recently, the National People's Congress released the Personal Information Protection Law, which became effective on November 1, 2021. The Personal Information Protection Law provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The Personal Information Protection Law also provides that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold to be set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the Personal Information Protection Law contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year and 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, 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.

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 and the Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings 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, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law 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. 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 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.

We are not currently required to obtain approval or prior permission from the CSRC or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to conduct a public offering in foreign capital markets. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such requirements, approvals or permissions in the future. We are required to obtain business licenses from Chinese authorities in connection with our general business activities currently conducted in China.

As of the date of this Quarterly Report on Form 10-Q, we are not required to obtain approval or prior permission from the CSRC or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to conduct a public offering in foreign capital markets. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such requirements, approvals or permissions in the future.

To operate our general business activities currently conducted in China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the State Administration for Market Regulation, or SAMR. Each of our Chinese subsidiaries has obtained a valid business license from the local counterpart of the SAMR, and no application for any such license has been denied.

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (the "M&A Rules") purport to require offshore special purpose vehicles that are controlled by Chinese companies or individuals and that have been formed for the purpose of seeking a public listing on an overseas stock exchange through acquisitions of Chinese domestic companies or assets in exchange for the shares of the offshore special purpose vehicles shall obtain CSRC approval prior to publicly listing their securities on an overseas stock exchange.

Based on the Chinese laws and regulations currently in effect, we are currently not required to obtain pre-approval from the CSRC to conduct a public offering in foreign capital markets, subject to interpretation of the existing Chinese laws and regulations by the Chinese government authorities. However, there remains some uncertainty as to how the M&A Rules will be interpreted or implemented, and its opinions summarized above are subject to any new laws, rules and regulations or detailed implementations and interpretations in any form relating to the M&A Rules. We cannot assure investors that relevant Chinese government agencies, including the CSRC, would reach the same conclusion.

Furthermore, on July 6, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly promulgated the Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law, pursuant to which Chinese regulators are required to accelerate rulemaking related to the overseas issuance and listing of securities, and update the existing laws and regulations related to data security, cross-border data flow, and management of confidential information. Numerous regulations, guidelines and other measures have been or are expected to be adopted under the umbrella of or in addition to the Cyber Security Law and Data Security Law. As there are still uncertainties regarding the interpretation and implementation of such regulatory guidance, we cannot assure investors that we will be able to comply with new regulatory requirements relating to our future overseas capital-raising activities and we may become subject to more stringent requirements with respect to matters including data privacy and cross-border investigation and enforcement of legal claims.

Based on the above and our understanding of the Chinese laws and regulations currently in effect, we were not required to submit an application to the CSRC or Cyberspace Administration of China (the "CAC") for the approval of our initial public offering and the listing and trading of our ADSs on the Nasdaq. However, there remains significant uncertainty as to the enactment, interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities. If it is determined in the future that the approval of the CSRC, the CAC or any other regulatory authority is required for offerings of our equity securities, we may face sanctions by the CSRC, the CAC or other Chinese regulatory agencies. These regulatory agencies may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operations in China, delay or restrict the repatriation of the proceeds from our initial public offering into China or take other actions that could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of our ADSs. In addition, if the CSRC, the CAC or other regulatory

agencies later promulgate new rules requiring that we obtain their approvals for any future public offerings, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Any uncertainties and/or negative publicity regarding such an approval requirement could have a material adverse effect on the trading price of the ADSs.

Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our product candidates.

The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product development activities, clinical trials, registration, production, distribution, packaging, labelling, storage and shipment, advertising, licensing and post-approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business. In order to commercialize our product candidates and manufacture and distribute pharmaceutical products in China, the third-party manufacturers, distributors or service providers with which we or our partners contract, as applicable, will be required to:

- obtain a pharmaceutical manufacturing permit for each production facility or active ingredient registration approval from the National Medical Products Administration of China (the "NMPA") and its relevant branches for the manufacture of our products;
- obtain a pharmaceutical distribution permit from the NMPA and its relevant branches for the distribution of our products; and
- renew the pharmaceutical manufacturing permits and the pharmaceutical distribution permits every five years, among other requirements.

If our partners' third-party manufacturers, distributors or service providers are unable to obtain or renew such permits or any other permits or licenses required for our operations, they will not be able to manufacture or distribute our product candidates and we will not be able to engage in the commercialization and distribution of our product candidates and our business may be adversely affected.

The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

Although the audit report included in our final prospectus dated October 31, 2021 and filed with the SEC on November 2, 2021 is prepared by U.S. auditors who are currently inspected by the PCAOB, there is no guarantee that future audit reports will be prepared by auditors that are completely inspected by the PCAOB and, as such, future investors may be deprived of such inspections, which could result in limitations or restrictions to our access of the U.S. capital markets. Furthermore, trading in our securities may be prohibited under the Holding Foreign Companies Accountable Act or the Accelerating Holding Foreign Companies Accountable Act if the SEC subsequently determines our audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely or the SEC identifies us as a Commission-Identified Issuer, and as a result, U.S. national securities exchanges, such as the Nasdaq, may determine to delist our securities. On June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act, which, if enacted, would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three.

As an auditor of companies that are registered with the SEC and publicly traded in the United States and a firm registered with the PCAOB, our auditor is required under the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Although we have substantial operations within China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese government authorities, our U.S. auditor is currently inspected by the PCAOB.

Inspections of other auditors conducted by the PCAOB outside China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from regularly evaluating auditors' audits and their quality control procedures. As a result, to the extent that any component of our auditor's work papers are or become located in China, such work papers will not be subject to inspection by the PCAOB. As a result, investors would be deprived of such PCAOB inspections, which could result in limitations or restrictions to our access of the U.S. capital markets.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular under Chinese law, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress which, if passed, would require the SEC to maintain a list of issuers for which PCAOB is not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on our Exchanges Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges such as the Nasdaq of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted. Furthermore, there have been recent deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. On May 20, 2020, the U.S. Senate passed the HFCA Act, which includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction. The U.S. House of Representatives passed the HFCA Act on December 2, 2020, and the HFCA Act was signed into law on December 18, 2020. Additionally, in July 2020, the U.S. President's Working Group on Financial Markets issued recommendations for actions that can be taken by the executive branch, the SEC, the PCAOB or other federal agencies and department with respect to Chinese companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States. In response, on November 23, 2020, the SEC issued guidance highlighting certain risks (and their implications to U.S. investors) associated with investments in China-based issuers and summarizing enhanced disclosures the SEC recommends China-based issuers make regarding such risks. On December 2, 2021, the SEC adopted amendments to finalize rules implementing the submission and disclosure requirements in the HFCA Act. We will be required to comply with these rules if the SEC identifies us as a Commission-Identified Issuer (as defined in the final rules) under a process to be subsequently established by the SEC, and the SEC could prohibit the trading of our securities on national securities exchanges if we are identified as a Commission-Identified Issuer. Under the HFCA Act, our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for three consecutive years, and this ultimately could result in our ADSs being delisted. Furthermore, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act, which, if enacted, would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three. On September 22, 2021, the PCAOB adopted PCAOB Rule 6100, Board Determinations Under the Holding Foreign Companies Accountable Act, implementing the HFCA Act, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCA Act, whether the Board is unable to inspect or investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction. PCAOB Rule 6100 establishes the manner of the PCAOB's determinations; the factors the PCAOB will evaluate and the documents and information it will consider when assessing whether a determination is warranted; the form, public availability, effective date, and duration of such determinations; and the process by which the PCAOB will reaffirm, modify or vacate any such determinations. Chairman Gensler emphasized, in his October 5, 2021 testimony before the House Committee on Financial Services, that the PCAOB's adoption of Rule

6100 was "an important step to meet its requirements under the [HFCA Act] to protect U.S. investors;" that "we remain on track to finalize its required rulemaking before the end of the year;" and that "it is critical that the [Securities and Exchange] Commission and the PCAOB work together to ensure that the audits of foreign companies accessing U.S. capital markets play by the same rules." On November 5, 2021, the SEC announced that it has approved Rule 6100.

Additionally, Nasdaq recently adopted additional listing criteria applicable to companies that primarily operate in jurisdictions where local regulators impose secrecy laws, national security laws or other laws that restrict U.S. regulators from accessing information relating to the issuer, or a Restrictive Market. Under the new rule, whether a jurisdiction permits PCAOB inspection would be a factor in determining whether a jurisdiction is deemed by the Nasdaq to be a Restrictive Market. China will likely be determined to be a Restrictive Market and, as a result, the Nasdaq may impose on us additional continued listing criteria or deny continued listing of our securities on the Nasdaq.

While we understand that there has been dialogue among the CSRC, the SEC and the PCAOB regarding the inspection of PCAOB-registered accounting firms in China, there can be no assurance that we will be able to comply with requirements imposed by U.S. regulators or Nasdaq. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules that may be adopted by the SEC under the HFCA Act (or, if enacted into law, the AHFCA Act). Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. The market price of our ADSs could be adversely affected as a result of anticipated negative impacts of these executive or legislative actions upon, as well as negative investor sentiment towards, companies with significant operations in China that are listed in the United States, regardless of whether these executive or legislative actions are implemented and regardless of our actual operating performance.

As a company with substantial operations outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

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

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the renminbi;
- changes in a specific country's or region's political or economic environment especially with respect to a particular country's treatment of or stance towards other countries;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States; and
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

If we fail to comply with Chinese environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, fire safety and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations primarily occur in China and involve the use of hazardous materials, including chemical materials. Our operations also produce hazardous waste products. We are therefore subject to Chinese laws and regulations concerning the discharge of waste water, gaseous waste and solid waste during our processes, including those relating to product development. We engage competent third-party contractors for the transfer and disposal of these materials and wastes. Despite our efforts to comply fully with environmental and safety regulations, any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, the shutdown of our facilities and the incurrence of obligations to take corrective measures. We cannot completely eliminate the risk of contamination or injury from these materials and wastes. In the event of contamination or injury resulting from the use or discharge of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil, administrative or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees and public liability insurance to cover costs and expenses that may be incurred if third parties are injured on our property, such insurance may not provide adequate coverage against potential liabilities. Furthermore, the Chinese government may take steps towards the adoption of more stringent environmental regulations, and, due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, our CROs may incur substantial capital expenditures to install, replace, upgrade or supplement their manufacturing facilities and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations and our business may be materially adversely affected.

China's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.

A majority of our operations are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China's economy differs from the economies of other countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. In recent years, the Chinese government has implemented measures emphasizing market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises. However, a significant portion of productive assets in China are still owned by the Chinese government. The Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policies, restricting the inflow and outflow of foreign capital and providing preferential treatment to particular industries or companies.

The Chinese government also has significant authority to exert influence on the ability of a China-based company, such as our company, to conduct its business. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

As the Chinese economy has become increasingly linked with the global economy, China is affected in various respects by downturns and recessions of major economies around the world. The various economic and policy measures enacted by the Chinese government to forestall economic downturns or bolster China's economic growth could materially affect our business. Any adverse change in the economic conditions in China, policies of the Chinese government or laws and regulations in China could have a material adverse effect on the overall economic growth of China and, in turn, our business.

Uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies in China could materially and adversely affect us.

We conduct our business primarily through our subsidiaries in China. Chinese laws and regulations govern our operations in China. Our subsidiaries are generally subject to laws and regulations applicable to foreign investments in China, which may not sufficiently cover all of the aspects of our economic activities in China. In addition, the implementation of laws and regulations may be in part based on government policies and internal rules that are subject to the interpretation and discretion of different government agencies (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not always be aware of any potential violation of these policies and rules. Such unpredictability regarding our contractual, property and procedural rights could adversely affect our business and impede our ability to continue our operations. Furthermore, since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and we may not receive the level of legal protection we enjoy than in more developed legal systems. These uncertainties could materially and adversely affect our business and results of operations.

On January 1, 2020, the Foreign Investment Law of the People's Republic of China ("Foreign Investment Law") took effect. The Foreign Investment Law imposes information reporting requirements on foreign investors and the applicable foreign invested entities. Non-compliance with the reporting requirements will result in corrective orders and fines between RMB100,000 and RMB500,000. The Foreign Investment Law imposes the duties of keeping trade secrets of foreign investors and foreign-invested entities confidential on the administrative authorities to protect intellectual property rights of foreign investors and foreign-invested entities. No administrative authorities or their staff members may compel technology transfer by administrative means or illegally reveal or provide trade secrets of foreign-invested entities to third parties.

Additionally, the NMPA's recent reform of the drug review and approval process may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our product candidates in a timely manner.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act (the "FCPA") and similar anti-corruption and anti-bribery laws of China and other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

Our operations are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of China and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for preclinical studies or clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. Conversely, for example, China's recently passed Anti-Foreign Sanctions Law may introduce counter, retaliatory measures against U.S. sanctions, which may cause some confusion and uncertainly over the regulatory sanctions landscape between the U.S. and China. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Restrictions on currency exchange may limit our ability to receive and use effectively financing in foreign currencies, including proceeds from our initial public offering.

Our Chinese subsidiaries' ability to obtain currency exchange is subject to significant foreign exchange controls and, in the case of transactions under the capital account, requires the approval of and/or registration with Chinese government authorities, including the State Administration of Foreign Exchange ("SAFE"). In particular, if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local branch of SAFE. If we finance our Chinese subsidiaries by means of additional capital contributions, these capital contributions are subject to registration with the State Administration for Market Regulation or its local branch, reporting of foreign investment information with the Ministry of Commerce of the People's Republic of China (the "MOFCOM") or its local branch or registration with other governmental authorities in China.

In light of the various requirements imposed by Chinese regulations on loans to, and direct investment in, China-based entities by offshore holding companies, we cannot assure investors that we will be able to complete the necessary government requirements or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our Chinese subsidiaries. If we fail to adhere to such requirements or obtain such approval, our ability to use the proceeds we received from our initial public offering and to capitalize or otherwise fund our Chinese operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

Chinese regulations relating to the establishment of offshore special purpose companies by residents in China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us.

In 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles ("SAFE Circular 37"). SAFE Circular 37 requires residents of China to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." The term "control" under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by residents of China in the offshore special purpose vehicles or Chinese companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by China residents, share transfer or exchange, merger, division or other material events. If the shareholders of the offshore holding company who are residents of China do not complete their registration with the local SAFE branches, the Chinese subsidiaries may be prohibited from making distributions of profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore parent company and from carrying out subsequent cross-border foreign exchange activities, and the offshore parent company may be restricted in its ability to contribute additional capital into its Chinese subsidiaries. Moreover, failure to comply with the SAFE registration and amendment requirements described above could result in liability under Chinese law for evasion of applicable foreign exchange restrictions.

Certain residents of China may hold direct or indirect interests in our company, and we will request residents of China who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not at all times be fully aware or informed of the identities of our shareholders or beneficial owners that are required to make such registrations, and we cannot provide any assurance that these residents will comply with our requests to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our China resident shareholders to comply with the registration procedures set forth in these regulations may subject us to fines or legal sanctions, restrictions on our cross-border investment activities or those of our China subsidiaries and limitations on the ability of our wholly foreign-owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to make distributions to our investors and other holders could be materially and adversely affected.

Chinese regulations establish complex procedures for some acquisitions of China-based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

Chinese regulations and rules concerning mergers and acquisitions including the M&A Rules and other regulations and rules with respect to mergers and acquisitions establish additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a Chinese domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have an impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or Chinese time-honored brand. Moreover, according to the Anti-Monopoly Law of the People's Republic of China promulgated on August 30, 2007 and the Provisions on Thresholds for Reporting of Concentrations of Undertakings issued by the State Council in August 2008 and amended in September 2018, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly enforcement agency of the State Council when the applicable threshold is crossed and such concentration

shall not be implemented without the clearance of prior reporting. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise "national defense and security" concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise "national security" concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises "national defense and security" or "national security" concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. As such our ability to expand our business or maintain or expand our market share through future acquisitions would be materially and adversely affected.

Our business may benefit from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies may have an adverse effect on our results of operations.

In the past, local governments in China have granted certain financial incentives from time to time to Chinese entities as part of their efforts to encourage the development of local businesses. To date, we have not received any financial incentives from local governments in China. The timing, amount and criteria of any government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to amend or terminate the relevant financial incentive policies or to reduce or eliminate incentives at any time. In addition, some government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to do so we may be deprived of the relevant incentives. To the extent we receive any financial incentives from local governments in China in the future, the reduction or elimination of such incentives may have an adverse effect on our results of operations.

If we are classified as a China resident enterprise for China income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders.

The Enterprise Income Tax Law of the People's Republic of China (the "EIT Law") which was promulgated in March 2007, became effective in January 2008 and was amended in February 2017 and December 2018, and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008 and as amended in April 2019, define the term "de facto management bodies" as "bodies that substantially carry out comprehensive management and control on the business operation, personnel, accounts and assets of enterprises." Under the EIT Law, an enterprise incorporated outside of China whose "de facto management bodies" are located in China may be considered a "resident enterprise" and will be subject to a uniform 25% enterprise income tax ("EIT") rate on its global income. The Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as Chinese Tax Resident Enterprises on the Basis of De Facto Management Bodies ("SAT Circular 82") issued by the State Taxation Administration of the People's Republic of China (the "SAT") on April 22, 2009 and as amended in November 2013 and December 2017 further specifies certain criteria for the determination of what constitutes "de facto management bodies." If all of these criteria are met, the relevant foreign enterprise may be regarded to have its "de facto management bodies" located in China and therefore be considered a Chinese resident enterprise. These criteria include: (i) the enterprise's day-to-day operational management is primarily exercised in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or subject to approval by organizations or personnel in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholders' meeting minutes are located or maintained in China; and (iv) 50% or more of voting board members or senior executives of the enterprise habitually reside in China. Although SAT Circular 82

only applies to foreign enterprises that are majority-owned and controlled by Chinese enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in SAT Circular 82 may be adopted by the Chinese tax authorities as the reference for determining whether the enterprises are Chinese tax residents, regardless of whether they are majority-owned and controlled by Chinese enterprises.

We believe that neither we nor any of our subsidiaries outside of China is a China resident enterprise for Chinese tax purposes. However, the tax resident status of an enterprise is subject to determination by the Chinese tax authorities, and uncertainties remain with respect to the interpretation of the term "de facto management body." If the Chinese tax authorities determine that we or any of our subsidiaries outside of China is a Chinese resident enterprise for EIT purposes, that entity would be subject to a 25% EIT on its global income. If such entity derives income other than dividends from its wholly-owned subsidiaries in China, a 25% EIT on its global income may increase our tax burden.

In addition, if we are classified as a China resident enterprise for Chinese tax purposes, we may be required to withhold tax at a rate of 10% from dividends we pay to our shareholders, including the holders of our ADSs, that are non-resident enterprises. Further, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10% Chinese withholding tax on gains realized on the sale or other disposition of ADSs or ordinary shares if such income is treated as sourced from within China. Furthermore, gains derived by our non-Chinese individual shareholders from the sale of our shares and ADSs may be subject to a 20% Chinese withholding tax. It is unclear whether our non-China-based individual shareholders (including our ADS holders) would be subject to any Chinese tax (including withholding tax) on dividends received by such non-Chinese individual shareholders in the event we are determined to be a China resident enterprise. If any Chinese tax were to apply to such dividends, it would generally apply at a rate of 20%. Chinese tax liability may vary under applicable tax treaties. However, it is unclear whether our non-China shareholders would be able to claim the benefits of any tax treaties between their country of tax residence and China in the event that we are treated as a China resident enterprise.

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.

We are a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, 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. If any of our Chinese subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us.

According to the Foreign Investment Law and its implementing rules, which jointly established the legal framework for the administration of foreign-invested companies, a foreign investor may, in accordance with other applicable laws, freely transfer into or out of China its contributions, profits, capital earnings, income from asset disposal, intellectual property rights, royalties acquired, compensation or indemnity legally obtained, and income from liquidation, made or derived within the territory of China in RMB or any foreign currency, and any entity or individual shall not illegally restrict such transfer in terms of the currency, amount and frequency. According to the Company Law of the People's Republic of China and other Chinese laws and regulations, our Chinese subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with Chinese accounting standards and regulations. In addition, each of our Chinese subsidiaries is required to set aside at least 10% of its accumulated after-tax profits, if any, each year to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Where the statutory reserve fund is insufficient to cover any loss the Chinese subsidiary incurred in the previous financial year, its current financial year's accumulated after-tax profits shall first be used to cover the loss before any statutory reserve fund is drawn therefrom. Such statutory reserve funds and the accumulated after-tax profits that are used for covering the loss cannot be distributed to us as dividends. At their discretion, our Chinese subsidiaries may allocate a portion of their after-tax profits based on Chinese accounting standards to a discretionary reserve fund.

Renminbi is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our Chinese subsidiaries to use any future renminbi revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of foreign currency may then restrict the ability of our Chinese subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. The renminbi is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Currently, our Chinese subsidiaries may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in renminbi to fund our business activities outside of China or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

In response to the persistent capital outflow in China and renminbi's depreciation against the U.S. dollar in the fourth quarter of 2016, the People's Bank of China ("PBOC") and the SAFE have promulgated a series of capital controls in early 2017, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments.

The Chinese government may continue to strengthen its capital controls, and more restrictions and substantial vetting processes may be put forward by SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our Chinese subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends or otherwise fund and conduct our business.

We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises.

The indirect transfer of equity interests in China resident enterprises by a non-China resident enterprise ("Indirect Transfer") is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. The Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises ("SAT Circular 7") sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise holding Chinese assets directly or indirectly in the course of a group's overseas restructuring, and the factors to be considered in determining whether an Indirect Transfer has a commercial purpose. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under Chinese laws: (i) 75% or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the Chinese taxable assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the asset value of the intermediary enterprise (excluding cash) is comprised directly or indirectly of investments in China, or 90% or more of its income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the Chinese taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non-Chinese tax payable on the gain derived from the indirect transfer of the Chinese taxable assets is lower than the potential Chinese income tax on the direct transfer of such assets. A transaction that does not satisfy all four tests in the immediate preceding sentence may nevertheless be deemed to lack a bona fide commercial purpose if the taxpayer cannot justify such purpose from a totality approach, taking into account the transferred group's value, income, asset composition, the history and substance in the structure, the non-Chinese tax implications, any tax treaty benefit and the availability of alternative transactions. Nevertheless, a non-resident enterprise's selling shares or ADSs of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 if the shares and ADSs were purchased on the public market as well and will not be subject to Chinese tax pursuant to SAT Circular 7.

However, as these rules and notices are relatively new and there is a lack of clear statutory interpretation, we face uncertainties regarding the reporting required for and impact on future private equity financing transactions, share exchanges or other transactions involving the transfer of shares in our company by investors that are non-Chinese resident enterprises, or the sale or purchase of shares in other non-Chinese resident companies or other taxable assets by us. For example, the Chinese tax authorities may consider that our most recent offering involves an indirect change of shareholding in our Chinese subsidiaries and therefore it may be regarded as an Indirect Transfer under SAT Circular 7. Although we believe no SAT Circular 7 reporting is required on the basis that the current offering has commercial purposes and is not conducted for tax avoidance, Chinese tax authorities may pursue us to report under SAT Circular 7 and request that we and our Chinese subsidiaries assist in the filing. As a result, we and our subsidiaries may be required to expend significant resources to provide assistance and comply with SAT Circular 7, or establish that we or our non-resident enterprises should not be subject to tax under SAT Circular 7, for the future offerings or other transactions, which may have an adverse effect on our and their financial condition and day-to-day operations.

Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the "Stock Option Rules"). In accordance with the Stock Option Rules and other relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our share incentive plan will be subject to such regulation. We plan to assist our employees to register their share options or shares. However, any failure of our Chinese individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors and employees under Chinese law.

Risks Related to our Financial Position, Need for Additional Capital, and Limited Operating History

We have incurred significant losses since our incorporation, have not generated any revenue from product sales to date and anticipate that we will continue to incur losses in the future and may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through private placements and through our initial public offering in November 2021. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our incorporation in July 2019. For the three months ended September 30, 2021 and 2020, our net losses were $13.1 million and $120.2 million, respectively. For the nine months ended September 30, 2021 and 2020, our net losses were $175.1 million and $126.9 million, respectively.

We expect to continue to incur losses in the foreseeable future, and we expect these losses to increase as we:

- continue our development and conduct preclinical studies and clinical trials of our product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- commercialize any of our product candidates for which we may obtain marketing approval;

- acquire or in-license other intellectual property, product candidates and technologies;
- hire additional clinical, operational, financial, business development, alliance management, quality control and scientific personnel;
- establish a sales, marketing and commercialization infrastructure for any products that obtain regulatory approval;
- obtain, maintain, expand and protect our intellectual property portfolio;
- enforce and defend intellectual property-related claims; and
- incur additional legal, accounting and other expenses associated with operating as a U.S.-listed public company.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining marketing approval for these product candidates and marketing and selling those product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our development efforts, expand our business or continue our operations. A decline in the value of our ADSs could cause our investors to lose all or part of their investment.

Our business model is designed to continue to in-license additional product candidates for development. We will likely need substantial additional funding for our current and future product development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.

Our operations have consumed substantial amounts of cash since our incorporation. The net cash used in our operating activities was $133.6 million and $49.3 million for the nine months ended September 30, 2021 and 2020, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our current clinical-stage product candidates and seek regulatory approval for these and other future product candidates. Our business model is designed to continue to in-license additional product candidates for development, and we expect to make significant upfront payments, milestone payments, and/or royalty payments to our current and any future licensing partners as we continue to advance the development and commercialization of our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We have also incurred and will continue to incur expenses as we create additional infrastructure to support our operations as a U.S. public company. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our development programs, future in-licensing of product candidates or any future commercialization efforts.

We believe our cash, cash equivalents and restricted cash as of September 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements through at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the extent to which we acquire or in-license other product candidates and technologies;
- the number and development requirements of the product candidates we pursue;
- the initiation, type, number, scope, progress, expansions, results, costs and timing of the preclinical studies and clinical trials of our product candidates, including those we may choose to pursue in the future;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory approval;
- the cash received, if any, from commercial sales of any product candidates for which we receive regulatory approval;
- our ability to achieve sufficient market acceptance, adequate coverage, and adequate market share and revenue for any approved products;
- the amount of revenue we receive pursuant to our in-license arrangements;
- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers, preclinical and clinical development personnel and commercial personnel; and
- the costs of operating as a U.S.-listed public company.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We will need to continue to rely on additional financing to achieve our business objectives. We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of holders of our ordinary shares or ADSs will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of holders of our ADSs. The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in our undertaking certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our ADSs to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

We have a very limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We commenced our operations in July 2019. Our operations to date have been limited to organizing and staffing our company, identifying potential partnerships and product candidates, acquiring or in-licensing product and technology rights and conducting development activities for our product candidates. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials. We have not yet obtained regulatory approval for, or demonstrated an ability to commercialize any of our product candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history and/or approved products on the market.

Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate, may make it difficult to evaluate our current business and prospects for future performance. Our short history makes any assessment of our future performance or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. In addition, as a new business, we may be more likely to encounter unforeseen expenses, difficulties, complications and delays due to limited experience. If we do not address these risks and difficulties successfully, our business will suffer.

Risks Related to our Business and Industry

Risks related to our development and commercialization of our product candidates

All of our product candidates are still in development in our licensed territories. If we are unable to advance our product candidates through preclinical and clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially adversely affected.

All of our product candidates are still in development in our licensed territories. Our ability to generate revenue from our product candidates is dependent on the receipt of regulatory approval and successful commercialization of such products, which may never occur. Each of our product candidates will require additional clinical development, regulatory approval in multiple jurisdictions, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales. The success of our product candidates will depend on several factors, including the following:

- sufficiency of our and our partners' financial and other resources to complete the necessary preclinical studies and clinical trials;

- successful enrollment in, and completion of, preclinical studies and clinical trials;
- obtaining positive results in our preclinical and clinical trials demonstrating efficacy, safety and, where applicable, durability of effect of our product candidates;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization;
- successful completion of all safety and efficacy studies, including studies that may be conducted outside of China, required to obtain regulatory approval in China and other jurisdictions for our product candidates;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- negotiating and executing supply agreements with our partners for clinical supply and commercial manufacturing of our product candidates;
- the ability of third-party manufacturers to establish and adapt their commercial manufacturing capabilities to the specifications for our product candidates for clinical supply and commercial manufacturing;
- obtaining and maintaining patent, trade secret and other intellectual property protection;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with other available therapies and alternative drugs;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following regulatory approval in China and other jurisdictions.

The success of our business is dependent upon our ability to develop and commercialize our clinical-stage product candidates, including, among others, mavacamten for the treatment of obstructive and non-obstructive hypertrophic cardiomyopathy (“oHCM” and “nHCM,” respectively), TP-03 for the potential treatment of Demodex blepharitis and Meibomian Gland Disease and NBTXR3 for the potential treatment of head and neck cancer and other solid tumors. With respect to certain of our product candidates, including NBTXR3, infigratinib, LYR-210, omilancor, and sisunatovir, we plan to join our partners’ planned and ongoing Phase 3 global clinical trials by enrolling patients in China and potentially other Asian markets to both expedite our partners’ global development programs and enable us to seek regulatory approval in China. As a result, our business is substantially dependent on our and our partners’ ability to complete the development of, obtain regulatory approval for, and successfully commercialize these and our other product candidates in a timely manner. If, for example, our partners change their Phase 3 clinical trial strategies for a product candidate or indication for which we had anticipated joining their Phase 3 global clinical trial, or if we do not succeed in independently developing, obtaining regulatory approval for, or commercializing our product candidates, we could experience significant delays in our ability to successfully commercialize product candidates, or be unable to commercialize product candidates at all.

We cannot commercialize product candidates in China without first obtaining regulatory approval from the NMPA. Similarly, we cannot commercialize product candidates in other jurisdictions outside of China without obtaining regulatory approval from comparable foreign regulatory authorities. The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly, both inside and outside of China, and approval may not be granted. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Even if our product candidates were to successfully obtain approval from the U.S. Food and Drug Administration (the “FDA”) and comparable foreign regulatory authorities, we would still need to seek approval in China and any other jurisdictions

where we plan to market the product. For example, we will need to conduct clinical trials of each of our product candidates in patients in China prior to seeking regulatory approval in China. Even if our product candidates have successfully completed clinical trials outside of China, there is no assurance that clinical trials conducted with Chinese patients will be successful. Any safety issues, product recalls or other incidents related to products approved and marketed in other jurisdictions may impact approval of those products by the NMPA. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations imposed on certain product candidates, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our product candidates or any other product candidate that we may in-license, acquire or develop in the future.

We are heavily dependent on the successful development and commercialization of our late-stage product candidates, including mavacamten, TP-03 and NBTXR3.

Our business and future success depends heavily on our ability to develop and commercialize our late-stage product candidates, including mavacamten, TP-03 and NBTXR3, and to satisfy the necessary regulatory requirements for their marketing and sale. If our clinical trials relating to these product candidates reveal safety and/or efficacy issues, we and our licensing partners may need to invest additional time and resources in research and development to attempt to remedy the issues identified. The development of the related product candidate could subsequently be impacted, which could potentially have a significant negative impact on our business prospects, financial condition and anticipated growth.

We may allocate our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must limit our development programs to specific product candidates that we identify for specific indications. Our business model is designed for us to continue to in-license additional product candidates for development. Our current financial and managerial resources may not be sufficient to successfully license or develop such product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements.

If safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with our product candidates, we may be unable to market such product candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain product candidates, including NBTXR3 and BBP-398, for use in combination with other cancer therapies. However, we have not developed or obtained regulatory approval for, and we do not manufacture or sell, any cancer therapies we plan to use or may use in combination with NBTXR3 or BBP-398. We may also seek to develop additional product candidates for use in combination with other therapeutics in the future.

Even if one or more of our product candidates, including NBTXR3 or BBP-398, were to receive regulatory approval for use in combination with cancer therapies, as applicable, or another therapeutic, we would continue to be subject to the risk that the NMPA or another regulatory authority could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing or supply issues could arise with one of these combination therapeutics. This could result in NBTXR3 or BBP-398 or one of our other products being removed from the market or being less successful commercially. Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved cancer therapy or therapeutic for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies and therapeutics face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse events, delays in

clinical trials, and lack of NMPA or other regulatory approval. If the NMPA or another regulatory authority revokes its approval of any cancer therapies or another therapeutic we may use in combination with NBTXR3 or BBP-398 or any of our other product candidates, we will not be able to market our product candidates in combination with such revoked cancer therapy or therapeutic.

We face substantial competition, which may result in our competitors discovering, developing or commercializing drugs before or more successfully than we do, or developing therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, including from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. For example, there are a number of large pharmaceutical and biotechnology companies that currently market drugs or are pursuing the development of therapies in the fields of cardiovascular disease, oncology, ophthalmic disease, respiratory disease and inflammatory disease. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to that of our product candidates. Potential competitors also include academic institutions, government authorities and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

An important part of our corporate strategy is to build a diversified product pipeline by acquiring or in-licensing and developing, or partnering to license and develop, product candidates that we believe are highly differentiated and have significant commercial potential. The acquisition or licensing of product candidates is very competitive and more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages over us, as may other emerging companies that take similar or different approaches to product acquisitions. We are aware of certain companies, including Zai Lab Limited and BeiGene, Ltd., that have business models that may compete directly with our own.

In addition, we face competition with respect to the indications for which we are pursuing our product candidates. For instance, there are a number of companies developing or marketing treatments globally and in China for hypertrophic cardiomyopathy (“HCM”), inflammatory bowel disease (“IBD”), respiratory syncytial virus (“RSV”), cholangiocarcinoma (“CCA”), non-small cell lung carcinoma (“NSCLC”) and gastric cancer, including many major pharmaceutical and biotechnology companies. For example, Cytokinetics, Inc., and its partner Ji Xing Pharmaceuticals are developing aficamten, a myosin inhibitor in development for the treatment for oHCM. Incyte Corporation and its partner Innovent Biologics, Inc. are developing pemigatinib, an FGFR inhibitor approved for the treatment of second line CCA in the United States, for the treatment of both frontline and second line CCA in China, and Amgen and its partner Zai Lab Limited are developing bemarituzumab (FPA144) for tumors that overexpress FGFR2b, including gastric and gastroesophageal junction cancers. There are also several programs in development targeting SHP2, including clinical programs run by Novartis AG, Revolution Medicines, Inc. and its partner Sanofi, Relay Therapeutics, Inc. and its partner Genentech, Inc. and Jacobio Pharmaceuticals Co. Ltd. and its partner AbbVie Inc. Programs in development for RSV include those run by ArkBio. There are a number of biologics that are approved or currently in development for the treatment of IBD, including therapeutics developed by AbbVie Inc. and Eli Lilly and Company.

Many of our competitors have significantly greater financial resources and expertise in conducting preclinical studies and clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration programs for clinical trials, as well as in acquiring or in-licensing technologies complementary to, or necessary for, our programs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain NMPA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours or acquire significant market share by being listed in the National Reimbursable Drug List (the "NRDL") before ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products.

Clinical development involves a lengthy and expensive process with an uncertain outcome.

There is a risk of failure for each of our product candidates. It is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we, including through the efforts of our partners, must conduct preclinical studies and must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete. The outcomes of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results of such clinical trial. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Future preclinical studies and clinical trials of our product candidates may not be successful.

Commencement of clinical trials is subject to finalization of the trial design based on ongoing discussions with the NMPA and/or other applicable regulatory authorities in the jurisdictions in which the clinical trials are being conducted, which could change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not anticipate. Successful completion of our clinical trials is a prerequisite to submitting a marketing authorization application to the NMPA and/or other regulatory authorities for each product candidate and, consequently, the ultimate approval and commercial marketing of our product candidates. We do not know whether the clinical trials for our product candidates will begin or be completed on schedule, if at all.

We, including through the efforts of our partners, may incur additional costs or experience delays in completing preclinical studies or clinical trials, or ultimately be unable to complete the development and commercialization of our product candidates.

We, including through the efforts of our partners, may experience delays in completing preclinical studies or clinical trials, and numerous unforeseen events could arise during, or as a result of, any future preclinical studies or clinical trials, which could delay or prevent us from receiving regulatory approval. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time or will be completed on schedule, if at all. We may experience numerous adverse or unforeseen events during, or as a result of, our or our partners' preclinical studies and clinical trials that could delay or terminate our clinical trials, or delay or prevent us from receiving marketing approval or commercialize our product candidates, including:

- Our partners may experience delays, for example with respect to the timing of their studies, pre-clinical studies, clinical trials, or regulatory reviews, which may influence the timing of our planned clinical development strategy;
- we may receive feedback from the NMPA or other relevant regulatory authorities that requires us to modify the design or implementation of our preclinical studies or clinical trials, impeding our ability to commence a clinical trial;

- we may experience delays in receiving, or may fail to receive, approval or written acknowledgment of the recordation filings we or our collaborating clinical trial sites submitted to the China Human Genetic Resources Administrative Office ("HGRAO") or comparable regulatory authorities;
- regulators or institutional review boards ("IRBs") or independent ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations ("CROs") who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- preclinical studies or clinical trials may fail to show safety or efficacy or otherwise produce negative or inconclusive results, or we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon product development programs;
- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- clinical trial sites, investigators, CROs or third-party contractors used in our or our partners' preclinical studies and our and our partners' clinical trials may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply, fail to meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators or engage new CROs or third-party contractors;
- the treatment conventions and approaches of individual physicians or hospitals and clinics may differ both locally and among our licensed territories, and may contribute to failures to comply with regulatory standards or maintain quality controls or deviations from clinical trial protocols, which would impact clinical trial operations and impact our ability to generate data consistent with that generated in our partners' global clinical trials;
- we may be unable to employ a companion diagnostic test to identify patients in a timely manner, or at all, who are likely to benefit from our product candidates;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our partners, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us;
- the supply or quality of our product candidates or other materials necessary to conduct preclinical studies and clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other potential therapies in the same product portfolios as our product candidates that raise safety or efficacy concerns about our product candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, the IRBs or ethics committees of the institutions at which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the NMPA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable

clinical protocols; inspection of the trial sites, laboratories or other participants of the clinical trial operations by the NMPA, HGRAO or other regulatory authorities that results in the imposition of a clinical hold; unforeseen safety issues or adverse events; failure to demonstrate a benefit from using a drug; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Further, the NMPA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Many of the factors or potential disruptions that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the lapse, revocation or denial of regulatory approval of our product candidates or the abandonment by us of such development programs.

If we are required to conduct additional clinical trials or testing of our product candidates, if we are unable to successfully complete clinical trials of our product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our product candidates;
- be unable to continue the clinical trial or carry out commercialization activities of a product candidate due to lapsed or revoked regulatory approval;
- not obtain regulatory approval at all;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements;
- encounter difficulties obtaining or be unable to obtain reimbursement for use of certain products;
- be subject to restrictions on the distribution and/or commercialization of products; and/or
- have the product removed from the market after obtaining regulatory approval.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could allow our competitors to bring products to market before we do or could result in the delay of our ability to successfully commercialize our product candidates until after the patents relevant to a particular product candidate have expired, harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we and our partners can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA or similar regulatory authorities. In particular, we expect to design our clinical trials to include some patients with specific genetic mutations or markers that may make them ideal candidates for treatment. These genetic mutations or markers, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable genetic mutations or markers. For example, in our planned Phase 3 clinical trial of infigratinib as part of the PROOF trial led by QED, we plan to focus on enrolling patients who have advanced, metastatic or inoperable CCA with FGFR2 gene fusions, which limits the total size of the patient population available for such trial and may cause delays in the clinical trial. In addition, our or our partners' ability to enroll patients may be delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point. The inability to enroll a sufficient number of patients with the applicable genetic mutation or marker or that meet other applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. For example, there are ongoing clinical trials, or we expect clinical trials to be initiated, in China of investigational therapeutic candidates for the treatment of CCA, HCM and RSV.

Patient enrollment may be affected by other factors, including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;
- the design and eligibility criteria for the clinical trial in question;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion;
- the availability of an appropriate genomic screening test;
- the regulatory approval required for conducting genomic screening tests;
- the perceived risks and benefits of the product candidate under study, including clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the availability and efficacy of competing therapies and clinical trials;
- the ability to monitor patients adequately during and after treatment;
- natural disasters or public health epidemics, such as the COVID-19 pandemic; and
- the proximity and availability of clinical trial sites for prospective patients.

If patients are unwilling to participate in our clinical trials for any reason, the timeline for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential product candidates may be delayed. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our ADSs to decline and limit our ability to obtain additional financing.

Interim, topline and preliminary data from preclinical studies or clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our or our partners' preclinical studies and our or our partners' clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim, topline or preliminary data by us, our partners or by our competitors could result in volatility in the price of our ADSs.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is derived from information that is typically extensive, and investors may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain regulatory approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Undesirable side effects and adverse events could delay or prevent the regulatory approval of our product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.

Undesirable side effects and adverse events that occur in our clinical trials could cause us to interrupt, delay or halt clinical trials or could cause regulatory authorities or IRBs to interrupt, delay or halt our clinical trials, and could also result in a more restrictive label or the delay or denial of regulatory approval by the NMPA or other regulatory authorities. In particular, as is the case with other oncology drugs, it is likely that there may be side effects, such as fatigue, nausea and low blood cell levels, associated with the use of certain of our oncology product candidates. For example, the known adverse events for infigratinib include temporary increases in the mineral phosphorus (also called phosphate) in the blood, temporary changes in kidney function, which are most frequently seen at the same time as the changes in phosphorus blood levels, and eye-related side effects (most frequently dry eye and blurry vision). Adverse events that have been observed in clinical trials of other SHP2 inhibitors include hematologic abnormalities and potential changes in regulation of serum electrolytes, particularly calcium and phosphorus. The results of our product candidates' trials could reveal a high and unacceptable severity and prevalence of these or other side effects, including undesirable side effects related to off-target toxicity. In addition, if any of our product candidates are tested or used in combination with other drugs, these combinations may have additional side effects, which could be more severe than those caused by either therapy alone. Any patient deaths or

severe side effects caused by our product candidates, or by therapies or therapeutic candidates of other companies that are thought to have similarities with our product candidates, or the use of our product candidates in combination with other drugs could result in the delay, suspension or termination of our clinical trials by us, an ethics committee, the NMPA or other regulatory authorities. The NMPA or comparable regulatory authorities could order us to cease further development of or deny or revoke approval of our product candidates for any or all targeted indications. The drug-related side effects or adverse events could adversely affect patient recruitment or the enrolled patients' ability or willingness to complete the trial, or could result in potential product liability claims or contract disputes. Any of these occurrences may harm our business, financial condition and prospects significantly. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, or if we fail to achieve market acceptance of any product candidate, the commercial prospects of such product candidates will be harmed and our ability to generate revenue from any of these product candidates would be delayed or eliminated.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive regulatory approval and we, our partners or others identify undesirable side effects or adverse events related to our product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- the NMPA or other comparable regulatory authorities may revoke or limit their approval of such product candidates;
- the NMPA or other comparable regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contra-indication or the revision of package insert;
- we may be required to create or revise a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of our product candidates;
- the NMPA or other comparable regulatory authorities may require a Risk Mitigation Plan ("RMP") or comparable report or plan (or analogous requirement) to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions, including being subject to fines, injunctions or the imposition of criminal or civil penalties;
- we may decide to remove such product candidates from the marketplace;
- the product candidates may become less competitive;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenue.

If we are unable to obtain NMPA approval for our product candidates to be eligible for accelerated review or approval pathway, the time and cost we incur to obtain regulatory approvals may increase. Even if our product candidates were to be qualified for accelerated review or approval, it may not lead to a faster development, review or approval process.

The 2020 Drug Registration Regulation and the auxiliary regulatory documents currently provide four procedures for fast-track review and approvals of drugs. The four procedures are (1) the review and approval

procedures for break-through therapeutic drugs; (2) the review and approval procedures for drug conditional approval application; (3) the priority review procedures for drug marketing authorization approval; and (4) drug special review and approval procedures in case of a public health emergency. The NMPA would prioritize the allocation of resources for communication, guidance, review, inspection, examination and approval of applications that are qualified for the application of the four procedures.

Although we may apply for fast-track review and approval of certain of our product candidates as a break-through therapy, for priority review, or for conditional approval, we may not be able to submit the application for break-through therapy designation or obtain the NMPA's approval for break-through therapy designation or priority review or obtain the NMPA's conditional approval for any of our product candidates in a timely manner, or at all. Even if granted, break-through therapy designation or priority review may not lead to faster development or accelerate the regulatory review or approval process. Moreover, such designation does not increase the likelihood that our product candidates will receive regulatory approval. If break-through therapy designation or priority review is not granted, our timeline for the development, regulatory approval and commercialization of our product candidates may be adversely affected and associated costs may increase. We may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our product candidates or any other product candidate that we may in-license, acquire or develop in the future if our product candidates fail to be qualified for any accelerated review and approval pathway, we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions or any approval contains significant limitations.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes. During the course of a development program, sponsors may also change the contract manufacturers used to produce the product candidates. Additionally, if we, through third parties, engage in the scale-up of manufacturing, we may encounter unexpected issues relating to the manufacturing process or the quality, purity and stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues. Such changes may not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of preclinical studies and clinical trials. Such changes may also require additional testing, notification or approval by the NMPA or other comparable regulatory authorities, including additional pharmacokinetics or pharmacodynamics trials. This could delay completion of preclinical studies and clinical trials; require us to conduct bridging clinical trials or studies, or to repeat one or more clinical trials; increase study or clinical trial costs; or delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

The incidence and prevalence for target patient populations of our product candidates are based on estimates and third-party sources. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analyses, and use such estimates in making decisions regarding our product development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in preclinical studies or clinical trials. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

Risks related to our business operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the expertise of the members of our development team, as well as the other principal members of our management team, including Yizhe Wang, Ph.D., our Chief Executive Officer, Yi Larson, our Chief Financial Officer, and Debra Yu, M.D., our President and Chief Strategy Officer. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time with one month's prior written notice. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified management, scientific, clinical, sales and marketing and other qualified personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs as part of a cross-border company in our key geographies. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, our management is required to devote significant time to new compliance initiatives from our status as a U.S. public company, which may require us to recruit more management personnel. Failure to succeed in our preclinical studies or clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

As we advance our development and commercialization plans and operate as a public company, we expect to need additional managerial, operational, financial and other personnel. We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of product development, regulatory affairs and business and commercial development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert the attention of our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and could have a materially adverse effect on our business.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market, distribute and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the NMPA or comparable regulatory authorities in other jurisdictions, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales, distribution and marketing operations. Without an internal commercial organization or the support of a third party to perform sales, distribution and marketing functions, we may be unable to compete successfully against these more established companies.

Product liability claims or lawsuits could cause us to incur substantial liabilities.

We face an inherent risk of product liability exposure related to the use of our product candidates in clinical trials or any product candidates we may decide to commercialize in the future. If we cannot successfully defend against claims that the use of such product candidates in our clinical trials or any products, including any of our product candidates which receive regulatory approval in the future, caused injuries, we could incur substantial liabilities and our relationship with our partner clinical trial sites may be adversely affected. Regardless of merit or eventual outcome, liability claims may result in:

- significant negative media attention and reputational damage;
- withdrawal of clinical trial participants or clinical trial sites or investigators and inability to continue clinical trials;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- the inability to commercialize any product candidates that we may develop;
- initiation of investigations by regulators;
- loss of revenue;
- a diversion of management's time and our resources; and
- a decline in the price of our ADSs.

In addition, our licensing partners are subject to similar product liability risks in the jurisdictions in which they operate. Any of these events could prevent us, our current partners or our potential future partners from achieving or maintaining market acceptance of the affected drug product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our drug products.

The Good Clinical Practices ("GCP") generally requires the study sponsor to purchase insurance for clinical trials. Except for the China GCP, existing Chinese laws and regulations do not require us to have, nor do we currently maintain, liability insurance to cover product liability claims. We do not have business liability or, in particular, product liability insurance for each of our product candidates. Any litigation might result in substantial costs and diversion of resources. While we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), this insurance may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with our collaborators.

Our internal information technology systems, or those used by our CROs, our licensors' CMOs or our other collaborators, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development and commercialization programs.

Despite the implementation of security measures, our internal information technology systems and those of our CROs, our licensors' contract manufacturing organizations ("CMOs") and our other collaborators, contractors and consultants are vulnerable to damage from internal or external events, such as computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, which compromise the confidentiality, integrity and availability of the systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development, gaining regulatory approval for our product candidates and commercialization efforts and our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical

information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could cause loss of data, damage to systems and data and leave us unable to utilize key business systems or access important data needed to operate our business, including our development activities or gaining regulatory approval for our product candidates. Our CROs, our licensors' CMOs and our other collaborators, contractors and consultants have and in the future may face similar risks, and service disruptions or security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we and our third-party vendors have on occasion experienced, and will continue to experience, threats to our or their data and systems, including malicious codes and viruses, phishing, business email compromise attacks, ransomware or other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data security and data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. We develop and maintain systems and controls designed to prevent these events from occurring, and we are establishing processes to identify and mitigate threats. The development and maintenance of these systems, controls and processes is costly and will require ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our CROs, our licensors' CMOs and our other collaborators, contractors or consultants, or our and their efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, ransomware, industrial espionage attacks or insider threat attacks that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in financial, legal, business or reputational harm to us.

Risks related to the regulation of our business

Our product candidates are subject to extensive regulation, and we cannot give any assurance that any of our product candidates will receive regulatory approval or be successfully commercialized.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export and post-approval pharmacovigilance compliance, are subject to comprehensive regulation by the NMPA and other regulatory authorities in China, and by comparable authorities in other countries where we may seek to obtain regulatory approval for our product candidates. We are not permitted to market any of our product candidates in China or other jurisdictions unless and until we receive regulatory approval from the NMPA and comparable regulatory authorities.

Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The Technical Guidelines for the Acceptance of Overseas Clinical Trial Data for Drugs published in 2018, for example, outlines the method by which foreign clinical data may be used to support an application. The Center for Drug Evaluation of the NMPA will assess data obtained from an overseas clinical trial to determine whether the data demonstrate the likelihood of ethnic sensitivity (*i.e.*, whether the overseas data includes enough Chinese patients to justify safety and efficacy for Chinese patients). If there is insufficient information or the data suggests ethnic inconsistencies in effectiveness and safety, we may be required to conduct a bridging pharmacokinetics trial in Chinese patients either before or in tandem with initiating a clinical trial in China, and any such clinical trial may not be able to replicate the efficacy and safety data from global trials. Securing regulatory approval may also require the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. The NMPA may also require a RMP or analogous requirement in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, certain of our product candidates, including LYR-210, could be reviewed for regulatory approval via the medical device pathway as opposed to the pharmaceutical candidate pathway. The NMPA and comparable regulatory authorities in other jurisdictions could decide to classify these product candidates as either a medical device or a drug, and such classification could impact the regulatory framework of such product's clinical development. Our development and commercialization plan for these product candidates is based on the assumption that they will be approved and classified as drugs. If any of our product candidates are considered to be medical devices in China, their development and commercialization process could potentially be longer and more costly than we anticipated. In addition, medical devices in China are not qualified for reimbursement under the NRDL, but are instead reimbursed either indirectly through reimbursement of medical service fees or directly by the Basic Medical Insurance if they are consumables/disposables. Our sales forecast for these product candidates may change if they were unable to be reimbursed separately by the Basic Medical Insurance.

We cannot provide any assurance that we will ever obtain regulatory approval for any of our product candidates or that any of our product candidates will be successfully commercialized, even if we receive regulatory approval. Our product candidates may not be effective, may be only moderately effective or may prove to have a high and unacceptable severity and prevalence of undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. In such an event, our clinical trials could be suspended or terminated and the NMPA or other relevant regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

The process of obtaining regulatory approvals in China and other countries is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. The regulatory process in China is also evolving and subject to change. Changes in regulatory approval policies, standards or procedures during the development period may require us to change our planned clinical trial designs or otherwise spend additional resources and effort to obtain clinical trial or marketing authorization approvals of our product candidates, and changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted marketing authorization application, pre-market approval or equivalent application type, may cause delays in the approval or rejection of an application. In addition, policy changes may result in significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. The NMPA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement with the NMPA or comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the NMPA or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- failure to satisfy the requirements of the NMPA or comparable regulatory authorities regarding regulatory inspections, including GCP, Good Supply Practices (“GSP”) or Good Manufacturing Practice (“GMP”), product conformity inspections and other routine or ad hoc inspections;
- failure to satisfy the requirements of the HGRAO or comparable regulatory authorities, or to obtain the HGRAO’s or comparable regulatory authorities’ approvals regarding the collection, use or outbound transfer of Chinese human genetic resources (“HGR”);
- failure of CROs, clinical trial sites or investigators to comply with the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH-GCP”) and the requirements of China GCP imposed by the NMPA;
- failure of the clinical trial results to meet the level of statistical significance required by the NMPA or comparable regulatory authorities for approval;
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the NMPA or comparable regulatory authorities;
- failure to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the NMPA or comparable regulatory authorities disagreeing with our interpretation of data from preclinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of an NDA or other submission or to obtain regulatory approval in China or elsewhere;
- the NMPA or comparable regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations of the NMPA or comparable regulatory authorities rendering our clinical data insufficient for approval;
- the NMPA or comparable regulatory authorities restricting the use of our products to a narrow population; and
- our CROs or licensors taking actions or inactions that materially and adversely impact the clinical trials and the regulatory application process.

In addition, even if we were to obtain approval, regulatory authorities may revoke approval, may approve any of our product candidates for fewer or more limited indications than we request, may monitor the price we intend to charge for our drugs or indirectly limit our ability to charge or change the price of our drugs, may grant

approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the NMPA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in China, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our product candidates, we may be subject to penalties.

If the NMPA or a comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for any such product candidate will be subject to extensive and ongoing regulatory requirements. These requirements may include submissions of safety and other post-marketing information and reports, facility registration and drug listing requirements, and continued compliance with Current Good Manufacturing Practice regulations (“cGMPs”), Good Laboratory Practices (“GLPs”) and GCPs. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials for the surveillance and monitoring the safety and efficacy of the product candidate.

Once a drug is approved by the NMPA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market or voluntary or mandatory drug recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring mediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, such as boxed warnings;

- imposition of a RMP, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil, administrative or criminal penalties; and
- revocation of approval of such drug.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost and we may not achieve or sustain profitability, which may harm our business, financial condition and prospects significantly.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate in Greater China and other Asian markets have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the Cyber Security Law, which became effective in June 2017, created China's first national-level data protection regime for "network operators," which may include all organizations in China that provide services over the internet or another information network.

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. With China's growing emphasis of its sovereignty over data derived from China, the outbound transmission of de-identified or pseudonymized health data for clinical trials may be subject to the new national security legal regime, including the Cyber Security Law, the Data Security Law, the Personal Information Protection Law, and various implementing regulations and standards. 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, 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.

Under the Cyber Security Law and the Measures on Standard, Safety and Service of the National Medical Care Big Data (Tentative), the transmission of certain personal information, important data and health and medical care big data outside of China is only permitted upon the completion of a security assessment conducted by or as determined by the Chinese government. Certain draft regulations, including the Measures for Security Assessment for Cross-border Transfer of Personal Information and Important Data (Draft for Comment), published in 2017, and the Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment), published in 2019, have been proposed by the Chinese government that specify the procedures and stipulate more detailed compliance requirements relating to such assessment, and in certain circumstances, government approval, prior to the transmission of such information and data outside of China.

In addition, the Standing Committee of the National People's Congress of the People's Republic of China ("SCNPC") promulgated the Data Security Law on June 10, 2021, which became effective on September 1, 2021. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities, and introduces a data classification and hierarchical protection system. The classification of data is based on its importance in economic and social development, as well as the degree of harm expected to be caused to national security, public interests, or legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used. The security assessment mechanism was also included in the Personal Information Protection Law, which was promulgated in August 2021 and became effective on November 1, 2021, for the Chinese government to supervise certain cross-border transfers of personal information.

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 will be 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 takes substantial time, effort and cost, and we may not be able to establish and maintain such systems fully as needed to ensure compliance with our legal obligations. Despite our investment, such systems may not fully guard us or enable us to appropriately respond to or mitigate all data security and network security risks or incidents we face. Furthermore, under the Data Security Law, data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, is to be processed and handled with a higher level of protection. The notion of important data is not clearly defined by the Cyber Security Law or the Data Security Law. In order to comply with the statutory requirements, we will need to determine whether we possess important data, monitor the important data catalogs that are expected to be published by local governments and departments, perform risk assessments and ensure we are complying 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 important data, and may need to pass the government security review or obtain government approval in order to share important data with offshore recipients, which can include foreign licensors, or share data stored in China with judicial and law enforcement authorities outside of China. If judicial and law enforcement authorities outside China require us to provide data stored in 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 impact on our operations in and outside of China.

Furthermore, in July 2021, the Cybersecurity Administration of China (the "CAC"), China's top cyberspace regulator, issued a proposed amendment to the Cybersecurity Review Measures ("Cybersecurity Review Measures") which have been in effect since June 1, 2020. Under the proposed amendment, the scope of entities required to undergo cybersecurity review to assess national security risks that arise from data processing activities would be expanded to include all critical information infrastructure operators who purchase network products and services and all data processors carrying out data processing activities that affect or may affect national security. In addition, the draft amendment proposed that all such entities that maintain or store the personal information of more than 1 million users and undertake a public listing of securities in a foreign country would be required to pass cybersecurity review, which would focus on the potential risk of core data, important data, or a large amount of personal information being stolen, leaked, destroyed, illegally used or exported out of China, or critical information infrastructure being affected, controlled or maliciously used by foreign governments after such a listing.

In October 2021, the CAC published the Measures on Security Assessment of Outbound Data Transfers (Draft for Comment) (the "Draft Measures"). The Draft Measures are enacted in accordance with the Cyber Security Law, the Data Security Law and the Personal Information Protection Law. Under the Draft Measures, the outbound transfer of data by a data processor would be subject to application of a security assessment under any of the following circumstances: (i) where the outbound data is personal information and important data collected and generated by critical information infrastructure operators; (ii) where the outbound data contains important data; (iii) where a personal information processor that has processed personal information of more than one million people transfers personal information overseas; and (iv) where the personal information of more than 100,000 people or sensitive personal information of more than 10,000 people is transferred overseas accumulatively; or (v) other circumstances under which a security assessment of outbound data transfers is required as prescribed by the CAC.

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, obtain government approval or certification, or put in place certain contractual protections before transferring personal information and human health-related data out of 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 China may be subject to such data localization requirements and heightened regulatory oversight and controls. To comply with these requirements, maintaining local data centers in China, conducting security assessments or obtaining the requisite approvals from the Chinese government for the transmission outside of China of such controlled information and data could significantly increase our operating costs or cause delays or disruptions in our business operations in and outside 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 or 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 adversely affect our ability to operate our business and our financial results.

The General Office of the State Council passed the Scientific Data Administrative Measures in March 2018, which provides a regulatory framework for the collection, submission, retention, exploitation, confidentiality and security of scientific data. Scientific data is defined as data generated from basic research, applied research, experiments and developments in the fields of natural sciences, engineering and technology. It also includes the original and derived data by means of surveillance, monitoring, field studies, examination and testing that are used in scientific research activities. All scientific data generated by research entities, including research institutions, higher education institutions and enterprises that is created or managed with government funds, or funded by any source that concerns state secrets, national security, or social and public interests, must be submitted to data centers designated by the Chinese government for consolidation. Disclosure of scientific data will be subject to regulatory scrutiny.

The definition of scientific data is quite broad, but the Chinese government has not issued further guidance to clarify if clinical study data would fall within the definition of scientific data. To our understanding, the Chinese government has not required life sciences companies to upload clinical study data to any government-designated data centers, or prevented the cross-border transmission and sharing of clinical study data. While we do not currently plan to utilize government funds when conducting our research and development activities, we may pursue some forms of government funding or support in the future. We plan to closely monitor legal and regulatory developments in this area to see how scientific data is interpreted, and we may be required to comply with additional regulatory requirements for sharing clinical study data with our licensors or foreign regulatory authorities, although the scope of such requirements, if any, is currently unknown.

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the Regulation on the Administration of Human Genetic Resources (the “HGR Regulation”) promulgated by the State Council of the People’s Republic of China (the “State Council”), which became effective on July 1, 2019, applies to activities that involve collection; biobanking; use of HGR, which includes the genetic materials with respect to organs, tissues, cells and other materials that contain the human genome, genes and other genetic substances (the “China Biospecimens”); and derived data, in China (together with the China Biospecimens, the “China-Sourced HGR”), and provision of such items to foreign parties. 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 out of China. Chinese parties are required to seek an advance approval for the collection of certain HGR and biobanking of all HGR. Approval for any export or cross-border transfer of China 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 HGRAO for record and obtain a notification filing number in order to transfer. The HGR Regulation also requires that foreign parties ensure the full participation of Chinese parties in international collaborations and share all records and data with the Chinese parties.

If the Chinese parties fail to comply with data protection 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 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, 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 China. So far, the HGRAO 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 HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAO to take rectification measures and was also banned by the HGRAO from submitting any clinical trial applications until the HGRAO was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in China until the ban was lifted. In another case, the CRO engaged by the Chinese subsidiary of a multi-national pharmaceutical company was found to have forged an ethics committee approval in order to accelerate the HGRAO approval. Both the Chinese subsidiary of the multi-national pharmaceutical company and the CRO were debarred from initiating new applications for a period of six to 12 months, respectively.

To further tighten the control of China 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, the illegal transfer of China-sourced biospecimens outside of China, and the transfer of China-sourced derived data to foreign parties or entities established or actually controlled by them without going through security review and assessment. 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 of the People's Republic of China ("PRC Biosecurity Law"), which became effective on April 15, 2021. The PRC Biosecurity Law will establish an integrated system to regulate biosecurity-related activities in China, including, among others, the security regulation of HGR and biological resources. The PRC Biosecurity Law for the first time expressly declares that 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 entities in China. Though the PRC Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives China's major regulator of HGR, the Ministry of Science and Technology, 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 China and elsewhere are often uncertain and in flux.

In addition, in the United States, at both the federal and state levels, and in territories outside of Mainland China where we have rights to and plan to develop and commercialize our in-licensed product candidates, including Hong Kong, Macau, Singapore, South Korea, Taiwan and Thailand, we are subject to laws and regulations that address privacy, personal information protection and data security. Numerous laws and regulations, including security breach notification laws, health information privacy laws and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

We expect that these data protection and transfer laws and regulations will receive greater attention and focus from regulators going forward, and we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under data protection, privacy and security laws in China, the United States and other countries where we plan or conduct business will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, result in the suspension of ongoing clinical trials or ban on initiation of new trials, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results

of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law, including the European Union General Data Protection Regulation, Cyber Security Law and HGR Regulation. 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.

Reimbursement may not be immediately available for our product candidates in China or other countries, which could diminish our sales or affect our profitability.

The regulations that govern pricing and reimbursement for pharmaceuticals vary widely from country to country. In China, the National Healthcare Security Administration ("NHSA") and its local counterparts, together with other government authorities, review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance, or the NRDL or provincial or local medical insurance catalogues for the national medical insurance program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy.

Historically, products included in the NRDL were typically generic and essential drugs. Innovative drugs were more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance. Since 2016, the government has started to include more innovative drugs in the NRDL through negotiations with marketing authorization holders of patented drugs, drugs with an exclusive source of supply and oncology drugs. On December 3, 2021, the NHSA published the 2021 NRDL, which included 74 additional drugs, among which 67 drugs with an exclusive source of supply were added to the 2021 NRDL via price negotiation with drug companies, resulting in an average price reduction of 61.71%.

We expect that most of our product candidates will be eligible for inclusion in the NRDL for the National Medical Insurance scheme, but the NHSA will likely expect that our products be in clinical use for some time before they are approved for inclusion. As a result, if we were to successfully launch commercial sales of our product candidates, our revenue from such sales will initially be self-paid by patients, which may make our product candidates less desirable. If the NHSA or any of its local counterparts accepts our application for the inclusion of our product candidates in the NRDL or provincial or local medical insurance catalogues, which may increase the demand for our product candidates, our potential revenue from the sales off our product candidates may still decrease as a result of lower prices we may be required to charge for our product candidates that are included in the NRDL or provincial or local medical insurance catalogues.

Moreover, eligibility for reimbursement in China or other countries does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including but not limited to licensing fees and costs incurred in development, distribution and sale. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in China or in other countries where we market our drugs. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

Risks Related to our In-Licensing Business Model and Dependence on Third Parties

If we breach our licenses or other intellectual property-related agreements for our product candidates or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.

Our business relies, in large part, on our ability to develop and commercialize product candidates we have licensed and sublicensed from third parties, including mavacamten from MyoKardia, TP-03 from Tarsus, infigratinib from QED, NBTXR3 from Nanobiotix, BBP-398 from Navire, LYR-210 from Lyra, sisunatovir from ReViral, and omilancor and NX-13 from Landos. Our licenses may not cover all intellectual property rights owned or controlled by our licensors and relevant to our product candidates. If we have not obtained a license to all intellectual property rights owned or controlled by our licensors that are relevant to our product candidates, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis, on commercially reasonable terms or at all. In addition, if our licensors breach such agreements, we may not be able to enforce such agreements against our licensors or their parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing to us the right to develop and commercialize the applicable product candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such product candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and intellectual property-related agreements also require us to comply with other obligations, including development and diligence obligations, providing certain information regarding our activities with respect to such product candidates and/or maintaining the confidentiality of information we receive from our licensors. For example, under our license agreement with MyoKardia, we are required to use commercially reasonable efforts to conduct the clinical, regulatory and other activities necessary to develop and commercialize mavacamten in the licensed territories in accordance with a development plan and a commercial plan, and MyoKardia may terminate the agreement if we fail to achieve certain key milestones. Our other license agreements include similar performance obligations and termination provisions.

If we fail to meet any of our obligations under our license and intellectual property-related agreements, our licensors may have the right to terminate our licenses and sublicenses and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses or sublicenses, we will lose the right to develop and commercialize our applicable product candidates and other third parties may be able to market product candidates similar or identical to ours. In such case, we may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. For example, if our agreement with Navire for BBP-398 terminates for any reason, we are required to grant Navire an exclusive license to certain of our intellectual property rights that cover inventions created by us solely or jointly with Navire in our performance of or exercise of our rights under our agreement with Navire or are used or applied as of the date of such termination in our development, manufacture or commercialization of BBP-398. Our license agreements with each of our other licensors contain similar provisions. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our product candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such product candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable product candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our ability to generate revenue and achieve profitability from third party licensed product candidates also depends upon our ability to retain exclusivity on the licensed product candidates and related product candidates controlled by the licensor. For example, under our agreement relating to BBP-398, Navire is required to grant us the first right to exclusively negotiate an exclusive license to develop, manufacture and commercialize certain compounds or products that Navire or its affiliates may acquire during the term of the license agreement to develop products or therapies in combination with BBP-398. However, we may fail to reach a definitive agreement during such negotiation period.

In addition, disputes may further arise regarding intellectual property subject to a license agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

Moreover, certain of our licensors do not own some or all of the intellectual property included in the license, but instead have licensed such intellectual property from a third party and have granted us a sub-license. For example, our licenses from QED, Navire, and Tarsus comprise sublicenses to us of certain intellectual property rights owned by third parties that are not our direct licensors. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our rights to the applicable licensed intellectual property may be terminated or narrowed, our exclusive licenses may be converted to non-exclusive licenses, and our ability to produce and sell our products and product candidates may be materially harmed.

Our licenses from MyoKardia, QED, Navire, Nanobiotix, Lyra, ReViral, Tarsus and Landos are limited to intellectual property rights under the control of such licensors. To the extent any of our licensors loses control over any of the intellectual property rights we license from them for any reason, we will no longer be licensed to such intellectual property rights to use, develop and otherwise commercialize our related product candidates. Any of the foregoing would have a material adverse effect on our business, financial conditions, results of operations and prospects.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or sublicensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

If we experience disruptions to our business relationships with our licensors, we could lose the ability to continue to source, develop and commercialize our product candidates, including ultimately losing our rights to such product candidates. For example, we have entered into an agreement with MyoKardia for clinical supply of mavacamten and also are working with MyoKardia on the regulatory approval process. If we are unable to secure clinical supply of mavacamten in a timely manner (or at all), we may suffer significant delays in the regulatory approval process, be unable to conduct clinical trials or fail to commercialize mavacamten in a timely manner (or at all). MyoKardia may terminate the agreement if we fail to achieve certain key milestones.

We rely on Perceptive Advisors ("Perceptive"), our founder and a significant shareholder in our company, as a source for identifying partners from which we may in-license product candidates. If Perceptive divests of its investment in our company or is no longer a significant shareholder, we may lose access to its expertise in sourcing opportunities and our business could be substantially harmed. Perceptive and its affiliates exercise significant influence over us, which may limit the ability of our investors and other holders to influence corporate matters and could delay or prevent a change in corporate control.

We rely in part on our relationship with Perceptive, our founder and a significant shareholder in our company, to implement our business strategy, including sourcing and identifying potential partners from which we may in-license product candidates for development. Perceptive has significant expertise in operational, financial, strategic and other matters key to our business strategy. This expertise has been available to us through the representatives Perceptive has had on our board of directors. As of December 1, 2021, Perceptive and its affiliates beneficially own 52.5% of our ordinary shares, based on the number of shares outstanding as of December 1, 2021. Because entities affiliated with Perceptive control a majority of the voting power of our outstanding ordinary shares, we are a controlled company (within the meaning of the Nasdaq rules). We intend to take advantage of corporate governance exemptions available to controlled companies, including exemptions from:

- the requirement that a majority of the board of directors consist of independent directors;
- the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- the requirement that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities.

As a result, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all of the Nasdaq corporate governance rules.

In addition, two of our non-employee directors are affiliated with Perceptive. As a result, Perceptive has the ability to substantially influence us, including through our elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Perceptive and its affiliates engage in a broad spectrum of activities, including investments in the healthcare industry generally. In the ordinary course of its business activities, Perceptive's interests may not always coincide with our corporate interests or the interests of minority holders of our ADSs, and it may exercise its voting and other rights in a manner with which other holders may not agree or that may not be in the best interests of our other shareholders. Perceptive may invest in or advise businesses that directly or indirectly compete with certain portions of our business or that are suppliers or customers of our company.

Our business model is designed to in-license additional product candidates for development. If Perceptive divests of its investment in our company or is no longer a significant shareholder, we may lose access to its expertise and would need to rely on other avenues, such as through our strategic collaboration agreements with Pfizer and BridgeBio, to source potential licensing partners and product candidates for development. In addition, conflicts of interest could arise in the future between us, on the one hand, and Perceptive and its affiliates and affiliated funds, including its and their current and future portfolio companies, on the other hand, concerning potential business opportunities, including potential licensing parties. Perceptive and its affiliated funds invest in companies that develop and commercialize drugs in global markets. As a result, Perceptive and its affiliates' and affiliated funds' current and future portfolio companies may now or in the future, directly or indirectly, compete with us for partnership and licensing opportunities.

We rely on our licensors and their contracts with third-party manufacturers to produce any product candidates for which we receive regulatory approval and engage in commercialization. If the manufacturing facilities of these third-party manufacturers are not approved by regulators, are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

We currently intend to rely on our licensors and their third-party manufacturers for the manufacture of the clinical and commercial supply of our product candidates. Our licensors will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and they may not be able to do so on favorable terms. Prior to being permitted to sell any drugs produced at these facilities, the facilities will need to be inspected and approved by regulatory authorities. If these facilities are not approved by regulators or are damaged or destroyed, or otherwise subject to disruption, our licensors may require substantial lead time to replace their manufacturing capabilities.

In such event, our licensors would be forced to identify and rely partially or entirely on alternative third-party CMOs for an indefinite period of time. Any new facility needed to replace an existing production facility would need to comply with the necessary regulatory requirements and be tailored to our licensors' production requirements and processes. We also would need regulatory approvals before using any products manufactured at a new facility in clinical trials or selling any products that are ultimately approved. If our licensors' third party manufacturers experience a shortage in supply, such shortage would have a negative impact on our business. Any disruptions or delays at the facilities of our licensors' third-party manufacturers or their failure to maintain regulatory compliance would impair our ability to develop and commercialize our product candidates, which would adversely affect our business and results of operations. In addition, any interruption of supplies may would adversely affect our business and results of operations. For example, the COVID-19 pandemic has had and could continue to have a broad impact on the production and supplies of active ingredients or other raw materials and result in a potential shortage of supply.

Our anticipated reliance on a limited number of third-party manufacturers through our licensing partners exposes us to a number of risks, including the following:

- our licensing partners be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our licensors' third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- CMOs may not be able to execute our licensors' manufacturing procedures and other logistical support requirements appropriately;
- our licensors' future CMOs may not perform as agreed, may not devote sufficient resources to our licensors' and our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products, if any;
- manufacturers may be subject to ongoing periodic unannounced inspection by regulatory authorities to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards, and we have no control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our licensors' third-party manufacturers in the manufacturing process for our product candidates;
- our licensors' third-party manufacturers could breach or terminate their agreements with our licensors;
- raw materials and components used in the manufacturing process, particularly those for which our licensors have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our licensors' CMOs and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our licensors' CMOs may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over the ability of our licensors' CMOs to maintain adequate quality control, quality assurance and qualified personnel.

We rely on third parties to conduct some of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely on third-party CROs to conduct some of our preclinical studies and clinical trials and monitor and manage data for certain of our preclinical studies and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the timing, conduct, and completion of our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we relied entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with GLP and the Regulations for the Administration of Affairs Concerning Experimental Animals or the Animal Welfare Act requirements. We and our CROs are required to comply with GCP and GLP regulations and guidelines enforced by the NMPA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure investors that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with ICH-GCP and China GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity and civil and criminal sanctions. Moreover, our business may be implicated if any of these third parties violates fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for which they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or compromised.

Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we lose our relationships with our CROs, our product development efforts could be delayed.

We rely on third-party vendors and CROs for some of our preclinical studies and clinical trials related to our product development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants

such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms, and we may not be able to meet our desired clinical development timelines.

We are dependent on third party manufacturers retained by our licensing partners for the manufacture of our product candidates and for our supply chain. If we or our licensing partners experience problems with any of these third parties, the manufacture of our product candidates or products could be delayed, which could harm our results of operations.

In order to successfully commercialize our product candidates, we currently intend to rely on our licensing partners to identify qualified CMOs for the scaled production of a commercial supply of certain of our product candidates. For a number of our product candidates, we or our licensing partners have not yet identified suppliers to support scaled production. If we or our licensing partners are unable to contract with CMOs for clinical and commercial supply of our product candidates, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. For example, we expect to source our clinical and commercial drug supply of mavacamten through a supply agreement with BMS, and any disruption or delay in the ability of BMS to manufacture and deliver mavacamten for our clinical trials, or any disruption in our planned supplier relationship with BMS, could harm our business, results of operations, financial condition and prospects. Similarly, we expect to source our clinical and commercial drug supply of TP-03 from Tarsus, and such supply is contingent upon Tarsus's ability to obtain adequate supply.

Our reliance on third-party manufacturers retained by our licensing partners to manufacture our product candidates entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on such third parties for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by such third parties because of factors beyond our control (including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by such third parties, based on their own business priorities, at a time that is costly or damaging to us.

In addition, the NMPA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and China GMP standards. Any failure by the third-party manufacturers retained by us or our licensing partners to comply with cGMP and China GMP standards or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the NMPA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or the imposition of civil and criminal penalties.

Any significant disruption in our potential supplier relationships could harm our business. We intend to source key materials from third parties, either directly through our licensors or indirectly through our licensors' agreements with suppliers or their manufacturers who have agreements with suppliers. We anticipate that, in the near term, all key materials will be sourced through third parties, including, for example, our clinical drug supply of mavacamten, which we expect to source under a clinical supply agreement with BMS. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture some of our drugs. Such suppliers may not sell these key materials to us or our licensors' manufacturers at the times we need them or on commercially reasonable terms. We currently do not have any agreements for the commercial production of these key materials. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If we or our licensors' manufacturers are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

If any manufacturer with which we or our licensors currently or may in the future contract fails to perform its obligations, we or our licensors, as applicable, may be forced to enter into an agreement with a different manufacturer, which we or our licensors may not be able to do on reasonable terms, if at all. In such a scenario, our clinical trials supply could be delayed significantly as we or our licensors establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we or our licensors may have difficulty, or there may be contractual restrictions prohibiting us or our licensors from, transferring such skills to a back-up or alternate supplier, or we or our licensors may be unable to transfer such skills at all. In addition, if we or our licensors are required to change manufacturers for any reason, we or our licensors will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. The delays associated with the verification of a new manufacturer could negatively affect our ability to advance clinical trials or otherwise develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently, which may increase our or our licensors' reliance on such manufacturer or require us or our licensors to obtain a license from such CMO in order to have another manufacturer manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Furthermore, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials.

Because of the complex nature of our compounds, we or our licensors' manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to complete large-scale clinical trials or make commercially successful products. In addition, as our product development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of our current licensors' suppliers may need to increase their scale of production to meet our projected needs for commercial manufacturing. Any failure on the part of our licensors' suppliers to meet our needs for commercial manufacturing could adversely impact our business and result of operations.

We depend on our licensors or patent owners of our in-licensed patent rights to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors or such patent owners to effectively protect these patent rights could adversely impact our business and operations.

We have licensed and sublicensed patent rights from third parties for our development programs, including mavacamten from MyoKardia, TP-03 from Tarsus, NBTXR3 from Nanobiotix, LYR-210 from Lyra, sisunatovir from ReViral, and omilancor and NX-13 from Landos. As a licensee and sublicensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. We cannot be certain that these patents and patent applications have been or will be prepared, filed, prosecuted or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover our product candidates. If our licensors or such third parties fail to prepare, prosecute or maintain such patent applications and patents, or lose rights to those patent applications or patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with certain of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. For example, under our license agreement with MyoKardia, MyoKardia has the first right to enforce the licensed patents in our licensed territory, subject to certain exceptions. MyoKardia also maintains the right to enforce such licensed patents in all other territories. Under our license agreement with Tarsus, we have the first right to enforce the licensed patents in our licensed field and territory. However, Tarsus maintains the sole right to enforce such licensed patents in all other territories, or if we do not elect to enforce the licensed patents against an infringement action within a specified timeframe of our notifying Tarsus or being notified by Tarsus of the infringement in our licensed territory. Each of our other license agreements contains similar provisions allocating rights to control the enforcement and defense of the licensed intellectual property.

Even if we are permitted to pursue the enforcement or defense of our licensed and sub-licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected.

Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our product candidates. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may wish to develop or commercialize our drug products. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the product candidates that we license from third parties. Moreover, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if we are permitted to pursue the enforcement or defense of our licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected.

In addition, our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights or other rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize drug products covered by these license agreements. If such licenses are terminated, we may be required to seek alternative in-license arrangements, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, we may need to modify or cease the development, manufacture and commercialization of one or more of our product candidates, and competitors would have the freedom to seek regulatory approval of and to market products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us, and our ability to successfully develop and commercialize any of our product candidates and technology may be adversely affected.

Our success depends, in part, on our ability to protect our proprietary technology and product candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights (whether owned or in-licensed), including patent rights. We seek to protect the product candidates and technology that we

consider commercially important by filing patent applications in the major pharmaceutical markets, including China and other countries and regions; relying on trade secrets or pharmaceutical regulatory protection; or employing a combination of these methods. We also seek to protect our proprietary position by in-licensing intellectual property relating to our technology and product candidates. If we or our licensors are unable to obtain or maintain intellectual property protection with respect to our product candidates and technology we develop or do not otherwise adequately protect our intellectual property, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we or our licensors may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications in all jurisdictions at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of our or their research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any patents we may own or in-license will have, or that any of our patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Furthermore, patents have a limited lifespan, and the term of any patents we may own or in-license may be inadequate to protect our competitive position of our product candidates or technology for an adequate amount of time.

Even if they are unchallenged, our patent applications, if issued, and any patents we may own or in-license, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent any patents we may own or in-license by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of any patent protection we may have. If the patent protection provided by our patents with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our development output, such as our employees, corporate collaborators, outside scientific collaborators, CMOs, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, China and the United States have adopted the “first-to-file” system under which the first party to file a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology that we invented.

In addition, under the Patent Law of the People’s Republic of China (the “Chinese Patent Law”), any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the China National Intellectual Property Administration (“CNIPA”) for confidentiality examination. Otherwise, in general, if an application is later filed in China, the patent right will not be granted. Moreover, even if patents do grant from any of the applications, the grant of a patent is not conclusive as to its scope, validity or enforceability. This added requirement of confidential examination by the CNIPA has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China. Currently, we do not have any invention patents granted to us by CNIPA and we do not have any invention patents under the application process. However, the CNIPA has granted to our partners 13 invention patents to our various partners related to our in-licensed assets.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates and the relevant patent offices or intellectual property courts may not agree with our interpretation as to whether we have patentable technology. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure investors that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our in-licensed patents may be challenged in the courts or patent offices in China and other countries and regions. We and our licensors may be subject to the submission of third-party opposition to the CNIPA against our pending application, or may become involved in invalidation proceedings or similar proceedings in foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our in-licensed patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we, or one of our licensors, may have to participate in proceedings on the ownership dispute of our licensor's invention or other features of patentability of our in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, the terms of patents are finite. The patents we in-license and the patents that may issue from our licensors' currently pending owned and in-licensed patent applications generally have a 20-year protection period starting from such patents and patent applications' earliest filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our in-licensed patents and our licensors' owned patents or patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For example, the compound patent for infigratinib expires in 2025, the compound patent for TP-03 expires in 2029 and the method patent for NBTXR3 expires in 2029, which, in each case, may be prior to or shortly after the time that such product candidates are commercialized.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

Our business relies, in part, on our ability to develop and commercialize product candidates we have licensed from third parties, and we have entered into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents and patent applications. Our licenses may not encumber all intellectual property rights owned or controlled by the affiliates of our licensors and relevant to our product candidates, and we may need to obtain additional licenses from our existing licensors and others to allow commercialization of product candidates we may develop. In such case, we may need to obtain additional licenses which may not be available on an exclusive basis, on commercially reasonable terms or at a reasonable cost, if at all. In addition, if our licensors breach the license agreements, we may not be able to enforce such agreements against our licensors' parent entity or affiliates. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable product candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such product candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such product candidates and/or maintaining the confidentiality of information we receive from our licensors.

If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses, we might not be able to develop, manufacture or market any drug or product candidate that is covered by the licenses provided for under these agreements and other third parties may be able to market product candidates similar or identical to ours. In such case, we may have to negotiate new or reinstated agreements with less favorable terms, and may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. We may also face claims for monetary damages or other penalties under these agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our product candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such product candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable product candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect our market exclusivity in China under the data exclusivity and monitoring surveillance period mechanisms.

In China, theoretically, market exclusivity of an innovative or improved new drug is protected via three mechanisms: patent exclusivity, data exclusivity, and monitoring surveillance period. According to the Implementing Regulations of the PRC Drug Administration Law, the Chinese government protects undisclosed data from drug studies and prevents the approval of an application by another company that uses the undisclosed data of an approved drug. It grants data exclusivity for a period of six years to data included in an NDA applicable to a new chemical entity. In practice, however, the NMPA has not established an effective mechanism to enforce data exclusivity. The NMPA issued a draft regulation on regulatory data protection on April 25, 2018 for public comments, but this draft regulation has yet to be finalized and implemented.

In addition, if an approved drug manufactured in China qualifies as an innovative drug or an improved new drug before December 1, 2019, such drugs will be eligible for a monitoring surveillance period for up to 5 years. During this post-marketing surveillance period, the NMPA will not accept marketing authorization applications filed by another company for the same product. In addition, the NMPA will not approve marketing authorization applications filed by another company to produce, change the dosage form of or import the drug while the innovative or improved new drug is under surveillance for the purpose of protecting public health. Therefore, this monitoring surveillance period provides a de facto exclusivity to locally manufactured innovative drugs or improved new drugs. Since our in-licensed assets are not locally manufactured and were not approved before December 1, 2019, we can only rely on patent exclusivity to protect our market exclusivity in China.

We may not be able to protect our intellectual property in China.

The validity, enforceability and scope of protection available under the relevant intellectual property laws in China are uncertain and still evolving. Implementation and enforcement of Chinese intellectual property-related laws have historically been deficient and ineffective. Accordingly, intellectual property and confidentiality legal regimes in China may not afford protection to the same extent as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant expenditure of cash and may divert management’s attention from our operations, which could harm our business, financial condition and results of operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Moreover, when we have in-licensed intellectual property, the decision as to the jurisdictions in which to seek protection may have already been made by the licensor. Consequently, we may not be able to prevent third parties from practicing our in-licensed inventions in countries where protection has not been sought and obtained. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions, including China. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in Greater China and the other Asian markets in which we operate, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Furthermore, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Developments in patent law could have a negative impact on our business.

Changes in either the patent laws or interpretation of the patent laws by authorities in China, the United States and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, including changing the standards of patentability, and any such changes could have a negative impact on our business. For example, the recent amendment to the Chinese Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, introduced patent extensions to eligible innovative drug patents, but lacks operational details. According to the Chinese Patent Law, the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products (if approved) without facing infringement risks. The adoption of this amendment may enable the patent owner to submit applications for a patent term extension. The actual length of any such extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to Chinese intellectual property laws would not have a negative impact on our intellectual property protection.

Similarly, in the United States, the Leahy-Smith America Invents Act (the “America Invents Act”), which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a “first-to-invent” system to a “first-to-file” system as of March 2013, changes to the way issued patents are challenged and changes to the way patent applications are disputed during the examination process. These include allowing third party submission of prior art to the U.S. Patent and Trademark Office (the “USPTO”) during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post grant proceedings, including post grant review, inter partes review and derivation proceedings. As a result of these changes, patent law in the United States may favor larger and more established companies that have

greater resources to devote to patent application filing and prosecution. The USPTO has developed regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective in March 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications and our ability to obtain patents based on our discoveries and to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. There could be similar changes in the laws of foreign jurisdictions that may affect the value of our patent rights or our other intellectual property rights. Any of the foregoing could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by registered patents and pending patent applications, we rely upon unpatented trade secret protection, unpatented know-how, continuing technological innovation and other proprietary information to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We also seek to protect our trade secrets and proprietary technology and processes, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our partners, collaborators, scientific advisors, employees, consultants, CROs and other third parties, and into confidentiality and invention or patent assignment agreements with our consultants and employees. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally disclosed or misappropriated our trade secrets, including through intellectual property litigations or other proceedings, is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts in China and other jurisdictions inside and outside the United States are less prepared, less willing or unwilling to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. For example, competitors could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts; willfully infringe, misappropriate or otherwise violate our intellectual property rights; design around our intellectual property protecting such technology; or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them, or others to whom they communicate it, from using that technology or information to compete against us, which may have a material adverse effect on our business, prospects, financial condition and results of operations. If we do not apply for patent protection or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Even if we are able to obtain patent protection for our product candidates, the life of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly with us after the expiration of our patent rights, if any, which would have a material adverse effect on our ability to successfully commercialize any product or technology.

The life of a patent and the protection it affords is limited. For example, in China, if all maintenance fees are timely paid, the natural expiration of an invention patent is 20 years from its application date. Even if we successfully obtain patent protection for an approved product candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the United States as well as the NMPA and the CNIPA in China, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. The pending patent applications, if issued, for our product candidates are expected to expire on various dates. Upon the expiration of our patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary intellectual property rights to product candidates for our development pipeline through acquisitions and in-licenses.

Our near-term business model is predicated, in large part, on our ability to successfully identify and acquire or in-license product candidates to grow our product candidate pipeline. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such product candidates from third parties on commercially reasonable terms or at all, including because we are focusing on specific areas of care such as cardiovascular and oncology. In that event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify product candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such product candidates. Any of the foregoing could have a materially adverse effect on our business, financial condition, results of operations and prospects.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for product candidates that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

The recent amendment to the Chinese Patent Law, which was promulgated by the SCNPC in October 2020 and took effect in June 2021, describes the general principles of patent term extension and patent linkage. The patent term extension provided by the amended Chinese Patent Law is similar to that under the Hatch Waxman Amendments. In July 2021, the NMPA and CNIPA jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (the "Measures on Patent Linkage"). The Measures on Patent Linkage describe a framework for patentees to defend their patent exclusivity and provides the conditions and procedures for the certification of non-infringement for generic companies and the marketing exclusivity period that may be granted to the first generic company receiving marketing authorization approval. As of the date of this Quarterly Report on Form 10-Q, no operational details have been published on the patent term extension, and uncertainties remain with respect to how the Chinese government will implement the patent term extension in China. As a result, the patents we have in-licensed or own in China may not be eligible to be extended for any patent term lost during the regulatory review process. In addition, an extension may not be granted because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors could face reduced barriers to marketing competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical data and launch their product earlier than might otherwise be the case. If we are unable to successfully challenge potential patent infringement or obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following or before our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to government patent agencies over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to patent agencies. The government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.

As of September 30, 2021, we had eleven trademark applications pending in Mainland China, four trademarks registered in Hong Kong, two trademarks registered in Singapore, two trademark applications pending in the United States, four trademark applications pending in Taiwan, four trademark applications pending in Macau, two trademark applications pending in South Korea, one trademark application pending in Thailand, two trademark applications in Cambodia, two trademark applications in Indonesia and two trademark applications in the Philippines. We may not be able to obtain trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- our competitors may be able to make products or product candidates that are similar to product candidates we are developing or may develop but that are not covered by the claims of the patents that we license or may own in the future;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future, which could result in the patents applied for not being issued or being invalidated after issuing;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to file patent applications covering certain inventions, which could result in the patents applied for not being issued or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents to which we hold rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we receive regulatory approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products or sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- third parties may gain unauthorized access to our intellectual property due to potential lapses in our information systems;
- the patents of others may harm our business; and

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may discover certain technologies containing such trade secrets or know-how through independent research and development and/or subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our owned or in-licensed patents could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our product candidates, our intellectual property rights could be challenged or invalidated. We or our licensors may become involved in patent litigation against third parties to enforce our owned or in-licensed patent rights, to invalidate patents held by such third parties or to defend against such claims. A court may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe, misappropriate or otherwise violate their intellectual property or that a patent we or our licensors have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In addition, third parties may initiate legal proceedings before administrative bodies in the United States or abroad, even outside the context of litigation, against us or our licensors with respect to our owned or in-licensed intellectual property to assert such challenges to such intellectual property rights. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates.

The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge include, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, lack of inventiveness, lack of written description or non-enablement. Grounds for an unenforceability assertion include, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information or made a misleading statement during prosecution. Although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. Even if we are successful in defending against such challenges, the cost to us of any patent litigation or similar proceeding could be substantial, and it may consume significant management and other personnel time. We do not maintain insurance to cover intellectual property infringement, misappropriation or violation.

An adverse result in any litigation or other intellectual property proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one or more of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidates. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Even if we establish infringement, a court of competent jurisdiction may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our current or future product candidates. Moreover, competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor’s patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business, financial condition, results of operations and prospects.

If our product candidates infringe, misappropriate or otherwise violate the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to sell and commercialize these product candidates.

Our commercial success depends significantly on our and our collaborators' ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

There may be issued third-party patents of which we are currently unaware and there may in the future be additional third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States, China and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our product candidates or technology. If any such patent applications issue as patents, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, or not infringed by our activities.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction or CNIPA could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such Chinese patent in CNIPA, we would need to overcome a presumption of validity. There is no assurance that the CNIPA would invalidate the claims of any such Chinese patent.

If we are found to infringe a third party's patent rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to:

- obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, if at all, and even if we were able to obtain such licenses, they could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing and royalty payments;
- defend litigation or administrative proceedings;
- reformulate product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very expensive and time consuming;

- cease developing, manufacturing and commercializing the infringing technology or product candidates; and
- pay such third party significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided consulting services to, other pharmaceutical companies including our competitors or potential competitors. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Even if we are successful in such litigations or administrative proceedings, such litigations and proceedings may be costly and time-consuming, regards of the outcome, and could result in a substantial diversion of management resources. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Any of the foregoing may have a material adverse effect on our business, prospects, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, if issued, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patent is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against which we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel for significant periods of time during such litigation could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

Intellectual property litigation may lead to unfavorable publicity, which may harm our reputation and cause the market price of our ADSs to decline, and any unfavorable outcome from such litigation could limit our development activities and/or our ability to commercialize our product candidates.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our ADSs may decline. Such announcements could also harm our reputation or the market for our product candidates, which could have a material adverse effect on our business.

In the event of intellectual property litigation, there can be no assurance that we would prevail, even if the case against us is weak or flawed. If third parties successfully assert their intellectual property rights against us, prohibitions against using certain technologies, or prohibitions against commercializing our product candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. Additionally, we may be required to obtain a license from the intellectual property owner in order to continue our development programs or to commercialize any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This may not be technically or commercially feasible, may render our products less competitive or may delay or prevent the launch of our products to the market. Any of the foregoing could limit our development activities, our ability to commercialize one or more product candidates, or both.

Many of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our preclinical studies and clinical trials, continue our internal research programs, in-license needed technology or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of competitors or their current or former employers or are in breach of non-competition or non-solicitation agreements with competitors or other third parties.

We could in the future be subject to claims that we or our employees, consultants or advisors have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of current or former employers, competitors or other third parties. Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not improperly use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have breached the terms of any non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer, competitor or other third parties.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and research personnel. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates if such technologies or

features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have a material adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in enforcing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, disputes may arise from conflicting obligations of consultants or others who are involved in developing our technology and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our owned and in-licensed patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to modify or cease the development, manufacture and commercialization of one or more of the product candidates we may develop, which could have a material adverse impact on our business.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture and commercialization of one or more of our product candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

Risks Related to Ownership of our ADSs and our Status as a Public Company

We are an "emerging growth company," as defined in the Securities Act, and a "smaller reporting company," as defined in the Exchange Act, and we cannot be certain if the reduced disclosure requirements applicable to us as an "emerging growth company" and a "smaller reporting company" will make our ADSs less attractive to investors.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act, and are taking advantage of, and may continue to take advantage of, certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, holders of our ADSs may not have access to certain information that they may deem important. We could be an emerging growth company for up to five years from the completion of our initial public offering, although circumstances could cause us to lose that status earlier, including if our total annual gross revenue exceeds $1.07 billion, if we issue more than $1.0 billion in non-convertible debt securities during any three-year period, or if the market value of our ordinary shares held by non-affiliates exceeds $700.0 million. We cannot predict if investors will find our ADSs less attractive because we rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard on the same timeline as other public companies, and we will not be able to revoke such election. This may make comparison of our financial statements with another emerging growth company that has not opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting ordinary shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting ordinary shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

We are incurring significantly increased costs as a result of operating as a U.S.-listed public company, and our management will devote substantial time to new compliance initiatives.

As a public company in the United States, we will continue to incur significant legal, accounting and other expenses globally that we did not incur previously. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel have been and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to establish and maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to file a report by our management on our internal control over financial reporting starting with our second Annual Report on Form 10-K. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The presence of material weaknesses in internal control over financial reporting could result in financial statement errors which, in turn, could lead to errors in our financial reports and/or delays in our financial reporting, which could require us to restate our operating results. To prepare for eventual compliance with Section 404, we are engaged in a process to document and evaluate our internal controls over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal controls over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal controls over financial reporting. Despite our efforts, we might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If we are unable to conclude that we have effective internal controls over financial reporting, investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, our ADSs may not be able to remain listed on the Nasdaq.

Recent litigation and negative publicity surrounding China-based companies listed in the United States may negatively impact the trading price of our ADSs.

We believe that recent litigation and negative publicity surrounding companies with operations in China that are listed in the United States has negatively impacted the stock prices of these companies. Certain politicians in the United States have publicly warned investors not to invest in China-based companies listed in the United States. The SEC and the PCAOB also issued a joint statement on April 21, 2020 reiterating the disclosure, financial reporting and other risks involved in investments in companies that are based in emerging markets, as well as the limited remedies available to investors who might take legal action against such companies. Furthermore, various equity-based research organizations have recently published reports on China-based companies after examining their corporate governance practices, related party transactions, sales practices and financial statements, and these reports have led to special investigations and listing suspensions on U.S. national exchanges. Any similar scrutiny regarding our company or business, regardless of its lack of merit, could cause the market price of our ADSs to fall, divert management resources and energy, cause us to incur expenses in defending ourselves against rumors, and increase the premiums we pay for director and officer insurance.

Uncertainties in the China legal system could materially and adversely affect us.

In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investments in China. However, China has not

developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. In particular, the China legal system is based on written statutes and prior court decisions have limited value as precedents. Since these laws and regulations are relatively new and the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules may not be uniform and enforcement of these laws, regulations and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the China legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

On July 6, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued a document to enhance its enforcement against illegal activities in the securities market and promote the high-quality development of capital markets, which, among other things, requires the relevant governmental authorities to strengthen cross-border oversight of law-enforcement and judicial cooperation, to enhance supervision over China-based companies listed overseas, and to establish and improve the system of extraterritorial application of the Chinese securities laws. Since this document is relatively new, uncertainties exist in relation to how soon legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on companies like us. It is especially difficult for us to accurately predict the potential impact to the Company of new legal requirements in China because the China legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value.

Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act.

In December 2012, the SEC instituted administrative proceedings under Rule 102(e)(1)(iii) of the SEC's Rules of Practice against China-based accounting firms alleging that these firms had violated U.S. securities laws and the SEC's rules and regulations thereunder by failing to provide to the SEC the firms' audit work papers with respect to certain China-based companies under the SEC's investigation. On January 22, 2014, the administrative law judge (the "ALJ") presiding over the matter rendered an initial decision that each of the firms had violated the SEC's rules of practice by failing to produce audit workpapers to the SEC. The initial decision censured each of the firms and barred them from practicing before the SEC for a period of six months. On February 12, 2014, certain of these China-based accounting firms appealed the ALJ's initial decision to the SEC. On February 6, 2015, the four China-based accounting firms each agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S.-listed companies. The settlement required the firms to follow detailed procedures and to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC in response to future document requests by the SEC made through the CSRC. If China-based accounting firms fail to comply with the documentation production procedures in the settlement agreement or if there is a failure of the process between the SEC and the CSRC, the SEC could restart the proceedings against the firms.

In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major Chinese operations may find it difficult or impossible to retain auditors in respect of their operations in China, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding China-based, United States-listed companies and the market price of our ADSs may be adversely affected.

If the accounting firms are subject to additional remedial measures, our ability to file our financial statements in compliance with SEC requirements could be impacted. A determination that we have not timely filed financial statements in compliance with SEC requirements would substantially reduce or effectively terminate the trading of our ADSs in the United States.

We do not currently intend to pay dividends on our securities, and, consequently, the ability of our investors to achieve a return on their investment will depend on appreciation in the price of our ADSs.

We have never declared or paid any dividends on our ordinary shares. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, investors are not likely to receive any dividends on their ADSs at least in the near term, and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that our ADSs will appreciate in value or even maintain the price at which our investors purchased their ADSs.

Active trading market may not continue to be developed or sustained and our investors may not be able to resell our ADSs at or above the price they paid, or at all.

Prior to our initial public offering, there was no public market in the United States for our ordinary shares or ADSs. Our ADSs are now listed on the Nasdaq Global Market. Our ordinary shares are not be listed on any other exchange, or quoted for trading on any over-the-counter trading system, in the United States.

We cannot assure investors that an active trading market for our ADSs will develop or be sustained, or that the market price of our ADSs will not fluctuate, including declining below the initial public offering price. If an active trading market for our ADSs does not develop or sustain itself, the market price and liquidity of our ADSs will be materially and adversely affected.

The market price for our ADSs may be volatile.

The market price for our ADSs is likely to be highly volatile and subject to wide fluctuations in response to factors, including the following:

- announcements of competitive developments;
- regulatory developments affecting us, our customers or our competitors;
- announcements regarding litigation or administrative proceedings involving us;
- actual or anticipated fluctuations in our period-to-period operating results;
- changes in financial estimates by securities research analysts;
- additions or departures of our executive officers;
- fluctuations of exchange rates between the renminbi and the U.S. dollar;
- release or expiration of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; and
- sales or perceived sales of additional ordinary shares or ADSs.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance. For example, in March 2020, the exchanges in the United States and China experienced a sharp decline as the COVID-19 pandemic negatively affected stock market and investor sentiment and resulted in significant volatility, including temporary trading halts. Prolonged global capital markets volatility may affect overall investor sentiment towards our ADSs, which would also negatively affect the trading prices for our ADSs.

Fluctuations in the value of the renminbi may have a material adverse effect on our results of operations and the value of any investment in our company.

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. On July 21, 2005, the Chinese government changed its decade-old policy of pegging the value of the renminbi to the U.S. dollar, and the renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the renminbi and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that the Chinese government would increase the flexibility of the exchange rate, and thereafter allowed the renminbi to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the renminbi by fixing its price against the U.S. dollar 1.9%, 1.6% and 1.1% lower than the previous day's value, respectively. On October 1, 2016, the renminbi joined the International Monetary Fund's basket of currencies that make up the Special Drawing Right, along with the U.S. dollar, the Euro, the Japanese yen and the British pound. In the fourth quarter of 2016, the renminbi depreciated significantly while the U.S. dollar surged and China experienced persistent capital outflows. With the development of the foreign exchange market and progress towards interest rate liberalization and renminbi internationalization, the Chinese government may in the future announce further changes to the exchange rate system. There is no guarantee that the renminbi will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or Chinese or U.S. government policy may impact the exchange rate between the renminbi and the U.S. dollar in the future.

Significant revaluation of the renminbi may have a material adverse effect on our results of operations and the value of any investment in our company. For example, to the extent that we need to convert U.S. dollars into renminbi for our operations, appreciation of the renminbi against the U.S. dollar would have an adverse effect on the renminbi amount we would receive from the conversion. Conversely, if we decide to convert our renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the renminbi would have a negative effect on the U.S. dollar amount available to us. In addition, appreciation or depreciation in the value of the renminbi relative to U.S. dollars would affect our financial results reported in U.S. dollar terms regardless of any underlying change in our business or results of operations.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by Chinese exchange control regulations that restrict our ability to convert renminbi into foreign currency.

Substantial future sales or perceived sales of our ADSs in the public market could cause the price of our ADSs to decline, even if our business is doing well.

Sales of our ADSs in the public market, or the perception that these sales could occur, could cause the market price of our ADSs to decline. As of December 1, 2021, 107,238,910 ordinary shares were outstanding, of which 20,906,116 ordinary shares were held in the form of American Depositary Shares. All ADSs sold in our initial public offering are currently freely transferable without restriction or additional registration under the Securities Act. The remaining ordinary shares outstanding after the initial public offering will be available for sale, subject to restrictions as applicable under Rule 144 under the Securities Act, beginning May 2, 2022, the expiration date of the 180-day lock-up arrangements entered into by our executive officers, directors and shareholders in connection with our initial public offering. There are certain exceptions to these lock-up arrangements. We cannot predict what effect, if any, market sales of securities held by our significant shareholders or any other shareholder or the availability of these securities for future sale will have on the market price of our ADSs.

In addition, we have filed a Form S-8 registering the issuance of approximately 24.9 million ordinary shares (which may be represented by ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Holders of ADSs have fewer rights than shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under our fifth amended and restated memorandum and articles of association, an annual general meeting and any extraordinary general meeting may be called with not less than seven calendar days' notice. When a general meeting is convened, holders of our ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw the ordinary shares underlying their ADSs to allow them to vote with respect to any specific matter. If we ask for instructions from such holders, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date and the depositary will send a notice about the upcoming vote and will arrange to deliver our voting materials to them. The depositary and its agents, however, may not be able to send voting instructions to them or carry out their voting instructions in a timely manner. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to such holders in a timely manner, but we cannot assure them that they will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. Holders or beneficial owner of ADSs may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if they wish us or the depositary to participate in legal proceedings. As a result, such holders may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they request. In addition, in their capacity as ADS holders, they will not be able to call a shareholders' meeting.

Investors may not receive distributions on our ADSs or any value for them if such distribution is illegal or impractical or if any required government approval cannot be obtained in order to make such distribution available to them.

Although we do not have any present plan to pay any dividends, the depositary of our ADSs has agreed to pay to our investors the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying our ADSs, after deducting its fees and expenses and any applicable taxes and governmental charges. Our investors will receive these distributions in proportion to the number of ordinary shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act but are not so properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that our investors may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available. These restrictions may cause a material decline in the value of our ADSs.

Our organizational and ownership structure may create significant conflicts of interests.

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and minority holders of our ADSs, on the one hand, and Perceptive and its shareholders, on the other hand. Two of our current non-employee directors have equity interests in Perceptive and, accordingly, their interests may be aligned with Perceptive's interests, which may not always coincide with our corporate interests or the interests of minority holders of our ADSs. In addition, we have entered into a Director Nomination Agreement with Perceptive that provides Perceptive the right to designate nominees for election to our board of directors so long as Perceptive beneficially owns 5% or more of the total number of shares that it owned as of the completion of our initial public offering. Perceptive may exercise its voting and other rights in a manner in

which our other holders may not agree or that may not be in the best interests of our other shareholders, including with respect to elections of directors, issuances of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Further, Perceptive and its affiliates engage in a broad spectrum of activities, including investments in the healthcare industry generally. Any change in our directors' Perceptive ownership could impact the interests of those holders.

In addition, we are party to certain related party agreements with Perceptive, including the Director Nomination Agreement. Perceptive and its shareholders, including certain of our directors, may have interests which differ from our interests or those of the minority holders of our ADSs. Perceptive may invest in or advise businesses that directly or indirectly compete with certain portions of our business or that are suppliers or customers of our company. Any material transaction between us and Perceptive or any other subsidiary of Perceptive will be subject to a related party transaction policy we have adopted, which will require prior approval of such transaction by our audit committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

Investors' right to participate in any future rights offerings may be limited, which may cause dilution to their holdings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to our investors in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary will not make rights available to our investors unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, our investors may be unable to participate in our rights offerings and may experience dilution in their holdings.

If we are classified as a passive foreign investment company, U.S. investors could be subject to adverse U.S. federal income tax consequences.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the average quarterly value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a "passive foreign investment company" ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are a PFIC for any taxable year during which a shareholder that is a United States person for U.S. federal income tax purposes (a "U.S. Holder") holds our ADSs, such U.S. Holder may suffer adverse U.S. federal income tax consequences, including having gains realized on the sale of our ADSs treated as ordinary income rather than capital gain, the loss of the preferential rate applicable to dividends received on our ADSs by individuals who are U.S. Holders, having interest charges apply to distributions by us and the proceeds of sales of our ADSs, and having additional reporting requirements. Additionally, if we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs, we will generally continue to be treated as a PFIC with respect to such U.S. Holder for all succeeding taxable years during which the U.S. Holder holds our ADSs (unless the investor timely makes a valid "deemed sale" election), even if we cease to meet the threshold requirements for PFIC status. A mark-to-market election may be available with respect our ADSs, which would result in U.S. federal income tax consequences to holders of our ADSs that are different from those described above.

Whether we are a PFIC for any taxable year is a factual determination made on an annual basis applying principles, methodologies and legal rules that in some circumstances are unclear and subject to varying interpretation. For instance, whether we are a PFIC for any taxable year depends on the composition and nature of our income and the composition, nature and value of our assets for the relevant taxable year. We do not believe we were a PFIC for our most recently completed taxable year, and we do not expect to become a PFIC in the current taxable year though there can be no assurances, including because the determination of whether a corporation will be a PFIC for any taxable year generally can only be made after the close of such taxable year. Because we hold, a substantial amount of passive assets, including cash, and because the value of our assets for purposes of the PFIC rules (including goodwill) may be determined by reference to the market value of our ADSs, which may be especially volatile due to the early stage of our product candidates, and by how, and how quickly, we use the cash proceeds we raise in any offering, including our initial public offering in our business, we cannot give any assurance that we will not be a PFIC for the current or any future taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the U.S. Internal Revenue Service (the "IRS") will agree with our determination and that the IRS would not successfully challenge our position.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs, whether or not such U.S. Holder makes a timely "qualified electing fund" or mark-to-market election may affect the U.S. federal income tax consequences to such U.S. Holder with respect to the acquisition, ownership and disposition of our ADSs. Shareholders should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ADSs.

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder (as defined above) is treated as owning (directly, indirectly or constructively) at least 10% of either the total value or total combined voting power of our ordinary shares, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" ("CFC") in our group (if any). We believe that we were a CFC for the taxable years ended December 31, 2019 and 2020. In addition, we believe that certain of our Subsidiaries were CFCs for the taxable years ended December 31, 2019 and 2020. We do not know whether we will be a CFC for the current tax year. Further, because our group includes at least one U.S. subsidiary that is classified as a corporation for U.S. federal income tax purposes, certain of our non-U.S. subsidiaries will be treated as CFCs (regardless of whether we are a CFC) for the current year. A United States shareholder of a CFC may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by such CFC, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether we are or any of our non-U.S. subsidiaries is treated as a CFC or whether such investor is treated as a United States shareholder with respect to any such CFC. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the reporting and tax paying obligations discussed above. For investors that are United States shareholders, failure to comply with these reporting obligations may subject them to significant monetary penalties and may prevent the statute of limitations with respect to their U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ADSs.

Our ability to use our NOLs to offset future taxable income may be subject to certain limitations.

We and certain of our subsidiaries are subject to tax in the United States. As of December 31, 2020 we had U.S. federal net operating losses ("NOLs") of approximately $22.7 million that do not expire. We also had foreign NOLs of approximately $1.4 million, which if not utilized, generally begin to expire in 2025. These NOLs could expire unused and be unavailable to offset future income tax liabilities. Certain of our subsidiaries may not generate U.S. taxable income in the future, in which case their NOLs will expire unused. U.S. federal NOLs generated in taxable years beginning after December 31, 2017 are generally not subject to expiration, but, for taxable years beginning after December 31, 2020, the deductibility of such NOLs is limited to 80% of our taxable income in any such taxable year. It is uncertain if and to what extent various states will confirm to the U.S. federal rules.

In addition, in general, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain shareholders over a three-year period, is subject to limitations on its ability to utilize its pre-change U.S. NOLs, research and development tax credit carryforwards and disallowed interest expense carryforwards to offset future taxable income. We have not performed an ownership change analysis as of December 31, 2020 or from our initial public offering. We may experience ownership changes in the future as a result of subsequent changes in our share ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change U.S. NOLs and other tax attributes to offset such taxable income may be subject to limitations.

There is tax risk associated with the reporting of cross-border arrangements and activities between us and our subsidiaries.

We are incorporated under the laws of the Cayman Islands and currently have subsidiaries in China, Hong Kong, the Cayman Islands, Singapore and the United States. If we succeed in growing our business we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

A tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

LianBio Licensing, LLC is the direct licensee of licenses from Navire, QED and MyoKardia and has assigned all rights and benefits under the licenses to other subsidiaries. This arrangement is subject to review by relevant tax authorities, including in the United States. If, for example, U.S. tax authorities were to treat LianBio Licensing, LLC, rather than the subsidiaries, as the initial owner of the applicable licenses that subsequently transferred the licenses to the subsidiaries, there could be a material adverse U.S. tax impact to us and our subsidiaries.

Changes in tax law may adversely affect our business and financial results.

Under current law, we expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. The Biden Administration has proposed significant changes to the existing U.S. tax rules, and there are a number of proposals in Congress that would similarly modify the existing U.S. tax rules, including a bill that has recently been passed by the U.S. House of Representatives. The likelihood of any such legislation being enacted is uncertain but could adversely impact us. Our actual tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities;

(3) changes in the valuation of our deferred tax assets and liabilities; (4) our ability to use NOL carryforwards to offset future taxable income and any adjustments to the amount of the NOL carryforwards we can utilize, and (5) changes in tax laws or the interpretation of such tax laws, and changes in U.S. GAAP.

Our investors may have difficulty enforcing judgments obtained against us.

We are a company incorporated under the laws of the Cayman Islands, and substantially all of our assets are located outside the United States. A majority of our current operations are conducted in China. In addition, some of our officers are nationals and residents of countries other than the United States. A substantial portion of the assets of these persons are located outside the United States. As a result, it may be difficult for our investors to effect service of process within the United States upon these persons. It may also be difficult for our investors to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors. In addition, there is uncertainty as to whether the courts of the Cayman Islands or China would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

The recognition and enforcement of foreign judgments are provided for under the Civil Procedures Law of the People's Republic of China (the "PRC Civil Procedures Law"). Chinese courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of reciprocity with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, Chinese courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of Chinese laws or national sovereignty, security or public interest. As a result, it is uncertain whether and on what basis a Chinese court would enforce a judgment rendered by a court in the United States.

We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under U.S. law, shareholders may have fewer shareholder rights than they would have under U.S. law and may face difficulties in protecting their interests.

We are an exempted company with limited liability incorporated in the Cayman Islands. Our corporate affairs are governed by our amended and restated memorandum and articles of association (as may be further amended from time to time), the Companies Act (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities law than the United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

In addition, as a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders of these companies with the exception that the shareholders may request a copy of the amended and restated memorandum and articles of association. Our directors have discretion under our amended and restated articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for our shareholders to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest. As a Cayman Islands company, we may not have standing to initiate a derivative action in a federal court of the United States. As a result, our shareholders may be limited in their ability to protect their interests if they are harmed in a manner that would otherwise enable them to sue in a U.S. federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in United States federal courts.

Some of our directors and executive officers reside outside of the United States and a substantial portion of their assets are located outside of the United States. As a result, it may be difficult or impossible for our shareholders to bring an action against us or against these individuals in the Cayman Islands or in China in the event that they believe that their rights have been infringed under the securities laws of the United States or otherwise. In addition, some of our operating subsidiaries are incorporated in China. To the extent our directors and executive officers reside in China or their assets are located in China, it may not be possible for investors to effect service of process upon us or our management inside China. Even if they are successful in bringing an action, the laws of the Cayman Islands and China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States or China, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a U.S. company.

Investors may be subject to limitations on transfers of their ADSs.

ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders, including holders who acquire ADSs in the secondary market, waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial.

If any holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, such holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and the depositary. If a lawsuit is brought against either or both of us and the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have, including results that could be less favorable to the plaintiffs in any such action. Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Holders of our ADSs or ordinary shares have limited choice of forum, which could limit their ability to obtain a favorable judicial forum for complaints against us, the depositary or our respective directors, officers or employees.

The deposit agreement governing our ADSs provides that, (i) the deposit agreement and the ADSs will be interpreted in accordance with the laws of the State of New York, and (ii) as an owner of ADSs, such owners irrevocably agree that any legal action arising out of the deposit agreement and the ADSs involving us or the depositary may only be instituted in a state or federal court in the city of New York. Any person or entity purchasing or otherwise acquiring any our ADSs, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions.

This choice of forum provision may increase cost for the holders of our ADSs or ordinary shares and limit their ability to bring a claim in a judicial forum that they find favorable for disputes with us, the depositary or our and the depositary's respective directors, officers or employees, which may discourage such lawsuits against us, the depositary and our and the depositary's respective directors, officers or employees. However, it is possible that a court could find either choice of forum provision to be inapplicable or unenforceable. The enforceability of similar choice of forum provisions has been challenged in legal proceedings. It is possible that a court could find this type of provisions to be inapplicable or unenforceable.

To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, actions by holders of our ADSs or ordinary shares to enforce any duty or liability created by the Exchange Act, the Securities Act or the respective rules and regulations thereunder must be brought in a federal court in the city of New York. Holders of our ADSs or ordinary shares will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

General Risk Factors

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

Our operations, and those of our and our partners' third-party research institution collaborators, clinical trial sites, CROs, CMOs, suppliers and other contractors and consultants could be subject to natural or man-made disasters, public health epidemics like the COVID-19 pandemic or other business interruptions, for which we are predominantly self-insured. The occurrence of any of these business interruptions could seriously harm our operations and financial condition and increase our costs and expenses. Through our partners, we also rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disasters, public health epidemics, such as the COVID-19 pandemic, or other business interruptions. Damage or extended periods of interruption to our or our vendors' corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, public health epidemics, pandemics or other events could cause us to delay or cease development or commercialization of some or all of our product candidates. Although we maintain insurance coverage on our facilities, our insurance might not cover all losses under such circumstances, including damage to third-party facilities, and our business may be seriously harmed by such delays and interruption. For example, the biotechnology sector has been impacted by the COVID-19 pandemic and could continue to experience negative impact to business operations. Although we have not been materially impacted by the COVID-19 pandemic to date, other outbreaks may occur, or there could be a resurgence of the COVID-19 pandemic, which could cause business disruptions in the future. Our or our partners' clinical development efforts could be delayed or otherwise negatively impacted, as patients may be reluctant or unable to go to hospitals or clinical testing sites to receive treatment. Additionally, the clinical supply of our product candidates could be negatively impacted due to reduced operations or a shutdown of our third-party manufacturing facilities, distribution channels and transportation systems, or shortages of raw materials and drug product.

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

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

For example, in December 2019, the COVID-19 pandemic began to impact the population in China, and since January 2020, the COVID-19 pandemic has spread around the world. COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including limiting non-essential travel. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism or employee turnover, disrupt our operations or increase the risk of a cybersecurity incident.

The extent to which the COVID-19 pandemic may continue to impact our business will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in China and the United States and other geographies where we or our partners and our and their third-party suppliers, clinical trial sites and CMOs or CROs operate. If we or any of the third parties with which we engage or on which we rely were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and results of operations.

In addition to in-licensing or acquiring product candidates, we may engage in future business acquisitions that may disrupt our business, cause dilution to our ADS holders and adversely affect our financial condition and operating results.

While we currently have no specific plans to acquire any other businesses, we may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue ordinary shares that would dilute our ADS holders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition candidates and we may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure our investors that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions could also pose numerous additional risks to our operations, including:

- problems integrating the acquired business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations.

If securities analysts do not publish research or reports about our business or if they publish inaccurate or negative evaluations of our business, the price of our ADSs could decline.

The trading market for our ADSs relies in part on the research and reports that industry or financial analysts publish about us or our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our ordinary shares, and such lack of research coverage may adversely affect the market price of our ADSs. If one or more of the analysts covering our business downgrade their evaluations of our ADSs or business or publishes inaccurate research about our business, the price of our ADSs could decline. If one or more of these analysts cease to cover our ADSs, we could lose visibility in the market for our ADSs, which in turn could cause the price of our ADSs to decline.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

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

(a) Recent Sales of Unregistered Equity Securities

Issuances of Ordinary Shares and Warrants

We believe that each of the following issuances was exempt from registration under the Securities Act in reliance on Regulation S under the Securities Act regarding sales by an issuer in offshore transactions, Regulation D under the Securities Act, Rule 701 under the Securities Act or pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering. No underwriters were used in the below issuances.

In March 2021, we issued three warrants exercisable for 125,000 ordinary shares of Lian Ophthalmology, one of our subsidiaries, in a private placement transaction. In October 2021 and November 2021, pursuant to an option agreement by and among LianBio, Lian Ophthalmology and the holder entered, we issued two warrants to purchase an aggregate of 156,746 of our ordinary shares at an exercise price of $0.000017100448 and 78,373 of our ordinary shares, respectively. Concurrently with such issuances, the warrants exercisable for 125,000 ordinary shares of Lian Ophthalmology were terminated.

In September 2021, Bing Li exercised certain of his vested options in accordance with their terms for 1,309,907 of the Company's ordinary shares.

On November 3, 2021, we filed a registration statement on Form S-8 under the Securities Act to register all of our ordinary shares subject to outstanding options and all of our ordinary shares otherwise issuable pursuant to our equity compensation plans.

(b) Use of Proceeds

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

Our initial public offering closed on November 3, 2021. In connection with the initial public offering, we granted the underwriters a 30-day option to purchase an additional 3,046,875 ADSs representing 3,046,875 ordinary shares. On December 1, 2021, pursuant to the partial exercise by the underwriters of such option, we issued an additional 593,616 ADSs representing 593,616 of our ordinary shares. The Company received gross proceeds of $334.5 million in connection with the IPO and subsequent exercise of the underwriters' options and aggregate net proceeds of $311.1 million after deducting underwriting discounts and commissions. In connection with our initial public offering, no payments were made by us to directors, officers or persons owning ten percent or more of our ordinary shares or to their associates or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 2, 2021. We are holding the balance of the net proceeds in cash, cash equivalents, and investments in short term, investment-grade interest-bearing securities such as money market funds, certificates of deposit, corporate bonds and commercial paper, and obligations of the U.S. government.

(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.

None.

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
3.1	Fifth Amended and Restated Memorandum and Articles of Association of LianBio (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40947), filed with the Securities and Exchange Commission on November 3, 2021)
4.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
4.2	Form of American Depositary Receipt (included in Exhibit 4.1).
4.3	Second Amended and Restated Shareholders Agreement dated October 28, 2020, by and among LianBio and the investors party thereto (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
4.4	Specimen Certificate evidencing the Ordinary Shares (incorporated by reference to Exhibit 4.4 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.5	Information Rights Letter of BridgeBio Pharma LLC, dated October 16, 2019, by and between the Company and BridgeBio Pharma LLC (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.6	Amended and Restated Option Agreement, dated as of August 10, 2020, by and among LianBio and MyoKardia, Inc. and QED Therapeutics, Inc. (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.7	Equity Holders Agreement, dated August 10, 2020, by and among LianBio, Lian Cardiovascular and MyoKardia, Inc. (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.8	Form of Warrant to Purchase Ordinary Shares, dated October 16, 2019, issued by Lian Oncology (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.9	Lian Cardiovascular Warrant to Purchase Ordinary Shares, dated August 10, 2020, issued by Lian Cardiovascular (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)

Exhibit No.	Description
4.10	Director Nomination Agreement, dated October 8, 2021, by and among LianBio and Perceptive Life Sciences Master Fund, Ltd., LEV LB Holdings, LP, Perceptive Xontogency Venture Fund, LP and C2 Life Sciences LLC (incorporated by reference to Exhibit 4.10 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
4.11	Form of Warrant to Purchase Ordinary Shares, dated October 18, 2021, issued by LianBio (incorporated by reference to Exhibit 4.11 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.12	Option Agreement, dated October 18, 2021, by and among LianBio, LianBio Ophthalmology and Tarsus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.12 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.13	Joinder Agreements to Second Amended and Restated Shareholders Agreement (incorporated by reference to Exhibit 4.13 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.14	Warrant to Purchase Ordinary Shares, dated October 18, 2021 issued by LianBio (incorporated by reference to Exhibit 4.14 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
10.1	Amendment No. 1 to Lease and Lease Agreement, dated as of July 1, 2021, between Carnegie 103 Associates, LLC and LianBio, LLC . (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.2	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.3	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among LianBio Licensing, LLC, Lian Cardviovascular, and LianBio relating to the Exclusive License Agreement, dated August 10, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc., as subsequently amended (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.4	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among Lian Cardviovascular, Lian Cardiovascular Limited and LianBio relating to the Exclusive License Agreement, dated August 10, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc., as subsequently amended (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.5	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among LianBio Licensing, LLC, Lian Oncology and LianBio relating to the Exclusive License Agreement, dated October 16, 2019, by and between LianBio and QED Therapeutics, Inc., as subsequently amended (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)

Exhibit No.	Description
10.6	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among Lian Oncology, Lian Oncology Limited and LianBio relating to the Exclusive License Agreement, dated October 16, 2019, by and between LianBio and QED Therapeutics, Inc., as subsequently amended (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.7	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among LianBio Licensing, LLC, Lian Oncology and LianBio relating to the Exclusive License Agreement, dated August 9, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc., as subsequently amended (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.8	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among Lian Oncology, Lian Oncology Limited and LianBio relating to the Exclusive License Agreement, dated August 9, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc., as subsequently amended (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.9	Amended and Restated Executive Employment Agreement, dated as of September 14, 2021, by and among LianBio, LianBio, LLC and Debra Yu, M.D. (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.10	Amended and Restated Executive Employment Agreement, dated as of September 14, 2021, by and among LianBio, LianBio, LLC and Brianne Jahn (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.11	LianBio 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.35 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.12	Form of Non-Statutory Share Option Agreement (Non-Employee Directors) (incorporated by reference to Exhibit 10.36 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.13	Form of Non-Statutory Share Option Agreement (Employees) (incorporated by reference to Exhibit 10.37 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.14	Form of Restricted Share Unit Agreement (Employees) (incorporated by reference to Exhibit 10.38 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.15	LianBio 2021 Cash Incentive Plan (incorporated by reference to Exhibit 10.39 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.16	LianBio Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.40 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)

Exhibit No.	Description
10.17	Lease Contract for Office Building of Corporate Avenue dated November 4, 2021, by and between Shanghai Xingqiao Real Estate Co., Ltd. and Shanghai LianBio Development Co., Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40947), filed with the Securities and Exchange Commission on November 10, 2021)
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.

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: January 10, 2022

By: /s/ Yizhe Wang

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

Date: January 10, 2022

By: /s/ Yi Larson

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

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/A of LianBio;

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

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

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

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

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

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

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

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

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

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

Date: January 10, 2022

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Yi Larson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: January 10, 2022

By: /s/ Yi Larson
Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q/A of LianBio (the "Company") for the quarterly period ended September 30, 2021 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 result of operations of the Company.

Date: January 10, 2022

By: /s/ Yizhe Wang
Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q/A of LianBio (the "Company") for the quarterly period ended September 30, 2021 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 result of operations of the Company.

Date: January 10, 2022

By: /s/ Yi Larson
Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)