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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q/A

(Amendment No. 1)

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

For the quarterly period ended June 30, 2023

OR

☐ **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: 001-41608

Structure Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Cayman Islands (State of Other Jurisdiction of incorporation or Organization)	**98-1480821** (I.R.S. Employer Identification No.)
601 Gateway Blvd., Suite 900 **South San Francisco, California** (Address of principal executive offices)	**94080** (Zip code)

Registrant's telephone number, including area code: (628) 229-9277

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

Title of Each Class	Name Of Each Exchange Trading Symbol(s)	On Which Registered
American Depositary Shares (ADSs), each representing three ordinary shares, par value $0.0001 per ordinary share	**GPCR**	**Nasdaq Global Market**
Ordinary shares, par value $0.0001 per share*		**Nasdaq Global Market***

* Not for trading, but only in connection with the registration of the American Depositary Shares

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 (§232.0405 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, a 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 ☒

The aggregate number of outstanding ordinary shares of the registrant, each with par value $0.0001 per share, as of August 3, 2023, was 114,805,483, comprised of 107,394,965 ordinary shares and 7,410,518 non-voting ordinary shares. 84,684,093 ordinary shares were held in the form of ADSs.

EXPLANATORY NOTE

Structure Therapeutics Inc., or “we,” “us,” and “our,” is filing this Amendment No. 1 on Form 10-Q/A (this “Amended Filing”) to amend our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (the “Quarterly Report”), which was originally filed with the Securities and Exchange Commission (“SEC”) on August 10, 2023 (the “Original Filing”). This Amended Filing is being filed solely for the purpose of indicating that an independent registered public accounting firm did not review the interim unaudited condensed consolidated financial statements as of and for the three and six months ended June 30, 2022 (the “2022 Interim Financial Statements”). As a result, the Quarterly Report is deemed substantially deficient until the reviews of the 2022 Interim Financial Statements are completed by an independent registered public accounting firm. The headings in the columns of the 2022 Interim Financial Statements and related notes thereto have been amended to state “Not Reviewed”. Except as described herein, no other changes have been made to the Original Filing. This Amended Filing speaks as of the filing date of the Original Filing and does not reflect events occurring after the filing date of the Original Filing or modify or update any of the other information contained in the Original Filing in any way other than as expressly described in this Amended Filing. Accordingly, this Amended Filing should be read in conjunction with the Original Filing. A review of the Company’s interim unaudited financial statements may result in changes to the financial statements contained herein. We plan to file an additional amendment to our Quarterly Report when the review is completed.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report"), contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "can," "will," "would," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical facts contained in this Quarterly Report, including without limitation statements regarding:

- the timing, progress and results of preclinical studies and clinical trials for our product candidates, including our product development plans and strategies;
- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- the potential benefits and market opportunity for our product candidates and discovery platform;
- expectations regarding the size, scope and design of clinical trials;
- our plans and strategy with respect to our drug discovery efforts and potential benefits of our discovery platform;
- our manufacturing, commercialization, and marketing plans and strategies;
- our plans to hire additional personnel and our ability to attract and retain such personnel;
- our estimates of the number of patients who suffer from the diseases we are targeting and potential growth in our target markets;
- our expectations regarding the approval and use of our product candidates;
- our competitive position and the development and impact of competing therapies that are or may become available;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- the rate and degree of market acceptance and clinical utility of product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our future financial performance;
- the period over which we estimate our existing cash, cash equivalents and short-term investments will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations; and
- the ongoing impact of geopolitical and macroeconomic factors.

The forward-looking statements in this Quarterly Report are only predictions and are based largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and

objectives, and financial needs. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of known and unknown risks, uncertainties, and assumptions, including those described under Part I. Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part II. Item 1A. “Risk Factors” elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and trends discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely upon these forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance, or achievements. The forward-looking statements made in this Quarterly Report relate only to events or information as of the date on which the statements are made in this Quarterly Report. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II. Item 1A. “Risk Factors” in this Quarterly Report. You should carefully consider these risks and uncertainties when investing in our American Depositary Shares (“ADSs”). The principal risks and uncertainties affecting our business include the following:

- We have a limited operating history and have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

- We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development programs, commercialization efforts or other operations.

- Our approach to the discovery of product candidates based on our technology platform is unproven, and we do not know whether we will be able to develop any products of commercial value.

- We are early in our development efforts and only have two product candidates, GSBR-1290 and ANPA-0073, in early clinical development. All of our other development programs are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

- Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes. The results of prior clinical trials and preclinical studies are not necessarily predictive of future results, and may not be favorable, or receive regulatory approval on a timely basis, if at all.

- Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

- Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates, any of which would limit the commercial potential of such product candidate.

- As an organization, we have never conducted later-stage clinical trials or submitted a New Drug Application ("NDA"), and may be unable to do so for any of our product candidates.

- The marketing approval processes of the U.S. Food and Drug Administration ("FDA") and applicable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.

- We have conducted, or plan to conduct, our initial clinical studies for GSBR-1290, ANPA-0073, LTSE-2578, and our other product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

- We rely on third parties for the manufacture of our product candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

- We intend to rely on third parties to conduct, supervise and monitor our discovery research, preclinical studies and clinical trials. If those third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

- We have entered into, and may in the future enter into, collaboration agreements and strategic alliances to maximize the potential of our structure-based drug discovery platform and product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

- Our existing discovery collaboration with Schrödinger, Inc. ("Schrödinger") is important to our business. If we are unable to maintain this collaboration, or if this collaboration is not successful, our business could be adversely affected.

- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

- We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may invest significant resources to develop these capabilities. If

we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

- We conduct certain research and development operations through our Australian wholly-owned subsidiaries. If we lose our ability to operate in Australia, or if any of our subsidiaries are unable to receive the research and development tax credit allowed by Australian regulations, or are required to refund any research and development tax credit previously received or reserve for such credit in our financial statements, our business and results of operations could suffer.

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

- If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

- We may rely on one or more in-licenses from third parties. If we lose these rights, our business may be materially adversely affected, and if disputes arise with one or more licensors, we may be subjected to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technologies covered by these license agreements.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

STRUCTURE THERAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(UNAUDITED)

	JUNE 30, 2023	DECEMBER 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 40,591	$ 26,091
Short-term investments	183,996	64,750
Prepaid expenses and other current assets	3,635	2,248
Total current assets	228,222	93,089
Property and equipment, net	1,078	1,031
Operating right-of-use assets	90	262
Other non-current assets	38	3,463
Total assets	$ 229,428	$ 97,845
Liabilities, redeemable convertible preferred shares and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 5,699	$ 6,009
Accrued expenses and other current liabilities	9,241	6,741
Operating lease liabilities, current portion	73	260
Total current liabilities	15,013	13,010
Total liabilities	15,013	13,010
Commitments and contingencies (Note 5)		
Series A redeemable convertible preferred shares – $0.0001 par value, 0 and 19,200 shares authorized, issued and outstanding as of June 30, 2023 and December 31, 2022, respectively (liquidation preference of $0 and $32,001 as of June 30, 2023 and December 31, 2022, respectively)	—	32,001
Series A+ redeemable convertible preferred shares – $0.0001 par value, 0 and 12,800 shares authorized, issued and outstanding as of June 30, 2023 and December 31, 2022, respectively (liquidation preference of $0 and $26,000 as of June 30, 2023 and December 31, 2022, respectively)	—	26,000
Series B redeemable convertible preferred stock – $0.0001 par value, 0 and 32,857 shares authorized, issued and outstanding as of June 30, 2023 and December 31, 2022, respectively (liquidation preference of $0 and $133,015 as of June 30, 2023 and December 31, 2022, respectively)	—	133,015
Series B-1 redeemable convertible preferred stock – $0.0001 par value, 0 and 2,161 shares authorized, issued and outstanding as of June 30, 2023 and December 31, 2022, respectively (liquidation preference of $0 and $7,000 as of June 30, 2023 and December 31, 2022, respectively)	—	8,959
Shareholders' equity (deficit):		
Undesignated shares – $0.0001 par value; 100,000 and 0 shares authorized as of June 30, 2023 and December 31, 2022, respectively	—	—
Non-voting ordinary shares – $0.0001 par value; 7,411 and 0 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1	—
Ordinary shares – $0.0001 par value; 500,000 and 432,982 shares authorized as of June 30, 2023 and December 31, 2022, respectively; 107,387 and 10,527 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	10	1
Additional paid-in capital	373,001	1,921
Accumulated other comprehensive loss	(390)	(110)
Accumulated deficit	(158,207)	(116,952)
Total shareholders' equity (deficit)	214,415	(115,140)
Total liabilities, redeemable convertible preferred shares and shareholders' equity (deficit)	$ 229,428	$ 97,845

The accompanying notes are an integral part of these condensed consolidated financial statements.

STRUCTURE THERAPEUTICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(UNAUDITED)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2023	2022 NOT REVIEWED[1]	2023	2022 NOT REVIEWED[1]
Operating expenses:				
Research and development	$ 19,411	$ 10,181	$ 32,546	$ 18,673
General and administrative	6,576	3,779	13,090	8,239
Total operating expenses	25,987	13,960	45,636	26,912
Loss from operations	(25,987)	(13,960)	(45,636)	(26,912)
Interest and other income (expense), net	2,825	76	4,524	7
Loss before provision for income taxes	(23,162)	(13,884)	(41,112)	(26,905)
Provision for income taxes	118	64	143	124
Net loss	(23,280)	(13,948)	(41,255)	(27,029)
Less: Accretion of redeemable convertible preferred shares to their redemption value	—	(1,515)	—	(1,515)
Net loss attributable to ordinary shareholders	$ (23,280)	$ (15,463)	$ (41,255)	$ (28,544)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.20)	$ (1.64)	$ (0.44)	$ (3.09)
Weighted-average ordinary shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	114,759	9,435	93,325	9,250
Other comprehensive loss:				
Unrealized loss on investments, net	(537)	(50)	(280)	(85)
Total other comprehensive loss	(537)	(50)	(280)	(85)
Comprehensive loss	$ (23,817)	$ (13,998)	$ (41,535)	$ (27,114)

The accompanying notes are an integral part of these condensed consolidated financial statements.

[1] A review, pursuant to PCAOB AS 4105, *Reviews of Interim Financial Information*, by an independent registered public accounting firm has not been completed for the indicated period.

STRUCTURE THERAPEUTICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)
(IN THOUSANDS)
(UNAUDITED)

	REDEEMABLE CONVERTIBLE PREFERRED SHARES								ORDINARY SHARES		NON-VOTING ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS EQUITY (DEFICIT)
	SERIES A		SERIES A+		SERIES B		SERIES B-1									
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance at December 31, 2022	19,200	$ 32,001	12,800	$ 26,000	32,857	$ 133,015	2,161	$ 8,959	10,527	$ 1	—	$ —	$ 1,921	$ (110)	$ (116,952)	$ (115,140)
Conversion of redeemable convertible preferred shares into ordinary shares upon initial public offering	(19,200)	(32,001)	(12,800)	(26,000)	(32,857)	(133,015)	(2,161)	(8,959)	67,018	7	—	—	199,968	—	—	199,975
Issuance of ordinary shares upon initial public offering, net of issuance costs and underwriting discount of $18,586	—	—	—	—	—	—	—	—	37,053	3	—	—	166,667	—	—	166,670
Net exercise of ordinary share warrants	—	—	—	—	—	—	—	—	106	—	—	—	—	—	—	—
Issuance of ordinary shares upon exercise of vested share options	—	—	—	—	—	—	—	—	26	—	—	—	31	—	—	31
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	2,533	—	—	2,533
Unrealized gain on investments, net	—	—	—	—	—	—	—	—	—	—	—	—	—	257	—	257
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(17,975)	(17,975)
Balance at March 31, 2023	—	—	—	—	—	—	—	—	114,730	11	—	—	371,120	147	(134,927)	236,351
Exchange of ordinary shares to non-voting ordinary shares	—	—	—	—	—	—	—	—	(7,411)	(1)	7,411	1	—	—	—	—
Issuance of ordinary shares upon exercise of vested share options	—	—	—	—	—	—	—	—	68	—	—	—	179	—	—	179
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	1,702	—	—	1,702
Unrealized loss on investments, net	—	—	—	—	—	—	—	—	—	—	—	—	—	(537)	—	(537)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(23,280)	(23,280)
Balance at June 30, 2023	—	$ —	—	$ —	—	$ —	—	$ —	107,387	$ 10	7,411	$ 1	$373,001	$ (390)	$ (158,207)	$ 214,415

	REDEEMABLE CONVERTIBLE PREFERRED SHARES								ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE LOSS	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' DEFICIT
	SERIES A		SERIES A+		SERIES B		SERIES B-1							
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance at December 31, 2021	19,200	$32,001	12,800	$26,000	24,702	$100,000	2,161	$8,959	10,894	$ 1	$ —	$ —	$ (64,736)	$ (64,735)
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	620	—	—	620
Unrealized loss on investments, net	—	—	—	—	—	—	—	—	—	—	—	(35)	—	(35)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(13,081)	(13,081)
Balance at March 31, 2022	19,200	$32,001	12,800	$26,000	24,702	$100,000	2,161	$8,959	10,894	$ 1	$ 620	$ (35)	$ (77,817)	$ (77,231)
Issuance of Series B redeemable convertible preferred shares, net of issuance costs of $1,515	—	—	—	—	8,155	31,500	—	—	—	—	—	—	—	—
Accretion of Series B redeemable convertible preferred shares to their redemption value	—	—	—	—	—	1,515	—	—	—	—	(620)	—	(895)	(1,515)
Repurchase of restricted stock awards	—	—	—	—	—	—	—	—	(450)	—	(6)	—	—	(6)
Issuance of ordinary shares upon exercise of vested share options	—	—	—	—	—	—	—	—	8	—	4	—	—	4
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	643	—	—	643
Unrealized loss on investments, net	—	—	—	—	—	—	—	—	—	—	—	(50)	—	(50)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(13,948)	(13,948)
Balance at June 30, 2022 (NOT REVIEWED)[1]	19,200	$32,001	12,800	$26,000	32,857	$133,015	2,161	$8,959	10,452	$ 1	$ 641	$ (85)	$ (92,660)	$ (92,103)

The accompanying notes are an integral part of these condensed consolidated financial statements.

[1] A review, pursuant to PCAOB AS 4105, *Reviews of Interim Financial Information*, by an independent registered public accounting firm has not been completed for the indicated period.

STRUCTURE THERAPEUTICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	SIX MONTHS ENDED June 30,	
	2023	2022
		NOT REVIEWED[1]
Cash flows from operating activities		
Net loss	$ (41,255)	$ (27,029)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	4,235	1,263
Depreciation	144	129
Non-cash lease expense	172	178
Amortization (accretion) of net investment premiums (discounts)	(1,990)	(147)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,387)	(990)
Other non-current assets	22	—
Accounts payable	122	12
Accrued expenses and other current liabilities	2,922	3,027
Operating lease liabilities	(187)	(177)
Deferred tax liability	—	121
Net cash used in operating activities	(37,202)	(23,613)
Cash flows from investing activities		
Purchases of short-term investments	(165,836)	(68,280)
Maturities of short-term investments	48,300	12,500
Purchases of property and equipment	(191)	(12)
Net cash used in investing activities	(117,727)	(55,792)
Cash flows from financing activities		
Proceeds from issuance of common stock in initial public offering, net of underwriting discount and commissions	172,296	—
Payments of deferred offering costs	(3,077)	(1,909)
Proceeds from issuance of Series B redeemable convertible preferred shares, net of issuance costs	—	31,500
Repurchases of restricted shares	—	(6)
Proceeds from exercise of share options	210	4
Net cash provided by financing activities	169,429	29,589
Net change in cash and cash equivalents	14,500	(49,816)
Cash and cash equivalents		
Beginning of the period	26,091	105,305
End of the period	$ 40,591	$ 55,489
Supplemental disclosures of noncash investing and financing activities		
Conversion of redeemable convertible preferred shares into ordinary shares upon initial public offering	$ 199,975	$ —
Exchange of ordinary shares to non-voting ordinary shares	$ 1	$ —
Deferred offering costs included in accounts payable and accrued expenses and other current liabilities	$ —	$ 348
Accretion of redeemable convertible preferred shares to their redemption value	$ —	$ 1,515

The accompanying notes are an integral part of these condensed consolidated financial statements.

[1] A review, pursuant to PCAOB AS 4105, *Reviews of Interim Financial Information*, by an independent registered public accounting firm has not been completed for the indicated period.

STRUCTURE THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(NOT REVIEWED)[1]

1. Organization and Nature of the Business

Structure Therapeutics Inc. (the "Company") is a clinical stage global biopharmaceutical company aiming to develop and deliver novel oral therapeutics to treat a wide range of chronic diseases with unmet medical needs. The Company was incorporated in February 2019 in the Cayman Islands, with operating subsidiaries in the United States and China. In June 2022, the Company changed its name from ShouTi Inc. to Structure Therapeutics Inc.

Initial Public Offering

On February 7, 2023, the Company closed its initial public offering ("IPO") of American Depositary Shares ("ADSs"). Each ADS represents three ordinary shares. The net proceeds from the IPO were approximately $166.7 million after deducting underwriting discounts and commissions and estimated offering costs.

Upon the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred shares converted into 67,018,087 ordinary shares. In connection with the completion of its IPO, the Company's memorandum of association was amended and restated to provide for 500,000,000 authorized ordinary shares with a par value of $0.0001 per share and 100,000,000 authorized undesignated shares with a par value of $0.0001 per share, of such class or classes as may be designated by the Company's board of directors in accordance with the Company's articles of association.

Liquidity and Capital Resources

The Company has incurred significant net operating losses and negative cash flows from operations since inception and had an accumulated deficit of $158.2 million as of June 30, 2023. Historically, the Company has financed its operations primarily through the private placement of equity securities. On February 7, 2023, the Company completed its IPO for net proceeds of approximately $166.7 million, after deducting underwriting discounts and estimated offering costs. As of June 30, 2023, the Company had cash, cash equivalents and short-term investments of $224.6 million.

The Company's condensed consolidated financial statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Based on its current business plan, the Company believes that its current cash, cash equivalents and short-term investments will be sufficient to fund its projected operations for at least 12 months from the date of the issuance of these condensed consolidated financial statements.

Impact of Geopolitical and Macroeconomic Factors

There may be significant uncertainty resulting from the impact of other geopolitical and macroeconomic factors, including global pandemics, inflation, supply chain issues, rising interest rates, future bank failures, increased geopolitical tensions between the U.S. and China and the impact of the Russia/Ukraine conflict.

[1] A review, pursuant to PCAOB AS 4105, *Reviews of Interim Financial Information*, by an independent registered public accounting firm has not been completed for the three and six months ended June 30, 2022.

STRUCTURE THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements and related disclosures have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. The functional and reporting currency of the Company and its subsidiaries is the U.S. dollar. The aggregate foreign currency transaction loss included in determining net loss was not material for the periods presented.

Unaudited Interim Financial Information

The condensed consolidated balance sheet as of December 31, 2022 was derived from the Company’s audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022, have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”), for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2022 and notes thereto, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 30, 2023. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company’s condensed consolidated financial position as of June 30, 2023 and condensed consolidated results of operations for the three and six months ended June 30, 2023 and 2022 and condensed consolidated cash flows for the six months ended June 30, 2023 and 2022 have been made. The results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements as well as the reported amounts of expenses during the reporting periods. Such estimates include lease liability, accruals for research and development activities, ordinary share valuation and related share-based compensation and certain other accrued liabilities. Actual results could differ from those estimates.

Concentration of Credit Risk

The Company is exposed to credit risk from its deposits of cash, cash equivalents and short-term investments in excess of the amount of insurance provided on such deposits. The Company invests its cash, cash equivalents and short-term investments in money market funds, corporate debt securities, U.S. government bonds and U.S. government agency bonds. The Company limits its credit risk associated with cash, cash equivalents and short-term investments by investing in investment-grade securities and using banks and institutions it believes are creditworthy. The Company has not experienced any losses on its deposits of cash, cash equivalents and short-term investments to date. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval prior to commercialization. These efforts require significant amounts of additional resources, adequate personnel, infrastructure and extensive compliance and reporting.

The Company's product candidates are still in development and, to date, none of the Company's product candidates have been approved for sale and, therefore, the Company has not generated any revenue from any of its products.

There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate any revenue from any of its products. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies.

The Company relies and expects to continue to rely on a small number of vendors to manufacture supplies and materials for its use in the clinical trial programs. These programs could be adversely affected by a significant interruption in these manufacturing services.

Credit Losses

For short-term investments in an unrealized loss position, the Company periodically assesses its portfolio for impairment. The assessment first considers the intent or requirement to sell the available-for-sale debt securities. If either of these criteria are met, the amortized cost basis will be written down to fair value through earnings.

If not met, the Company evaluates whether the decline resulted from credit losses or other factors by considering the extent to which fair value is less than amortized cost, any changes to the rating of the short-term investments by a rating agency, and any adverse conditions specifically related to the short-term investments, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the short-term investments is compared to the amortized cost basis of the short-term investments. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded, with a corresponding adjustment to interest and other income (expense), net, limited by the amount that the fair value is less than the amortized cost basis. The Company has elected to exclude accrued interest from both the fair value and the amortized cost basis of the available-for-sale debt securities for the purposes of identifying and measuring an impairment. The Company writes off accrued interest as a reduction of interest income when an issuer has defaulted on interest payments due on a security. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive loss.

Fair Value of Financial Instruments

The Company establishes the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and established a fair value hierarchy based on the inputs used to measure fair value.

The carrying value of cash and cash equivalents, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy which establishes three levels of inputs that may be used to measure fair value (see Note 4. Fair Value Measurements).

Deferred Offering Costs

The Company capitalizes, within other non-current assets, certain legal, accounting and other third-party fees that are directly related to the Company's in-process equity financings, including its IPO, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the offering. Should a planned equity financing be abandoned, terminated or significantly delayed, the deferred offering costs will be immediately written off to general and administrative expenses. Upon closing the IPO, all deferred offering costs were charged against the proceeds from the IPO and recorded in shareholders equity (deficit) as a reduction of additional paid-in capital. As of June 30, 2023, there were no deferred offering costs recorded on the condensed consolidated balance sheets.

Net Loss Per Share Attributable to Ordinary Shareholders

Basic net loss per ordinary share is calculated by dividing the net loss attributable to ordinary shareholders by the weighted-average number of ordinary shares, including non-voting ordinary shares, outstanding during the period, without consideration of potentially dilutive securities. Net loss attributable to ordinary shareholders is computed as net loss less accretion of redeemable convertible preferred shares. Diluted net loss per share is computed by dividing the net loss attributable to ordinary shareholders by the weighted-average number of ordinary shares, including non-voting ordinary shares, and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred shares, ordinary share warrants, unvested restricted ordinary shares subject to repurchase and share options are considered to be potentially dilutive securities. Basic and diluted net loss per share attributable to ordinary shareholders is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred shares are considered a participating security because they participate in dividends with ordinary shares. The holders of redeemable convertible preferred shares do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to ordinary shareholders, including non-voting ordinary shares. Because the Company has reported a net loss for all periods presented, diluted net loss per ordinary share is the same as basic net loss per ordinary share for those periods.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Account Standards Update ("ASU") No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a

reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. The amendments in this Update are effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted ASU 2016-13 as of January 1, 2023 and the adoption did not have a material impact on the Company's unaudited interim condensed consolidated financial statements and related disclosures.

3. Composition of Certain Consolidated Financial Statement Line Items

Property and equipment, net consists of the following (in thousands):

	JUNE 30, 2023	DECEMBER 31, 2022
Laboratory equipment	$ 1,267	$ 1,098
Furniture and fixtures	115	115
Computer equipment and software	80	58
Leasehold improvements	109	109
	$ 1,571	$ 1,380
Less: Accumulated depreciation	(493)	(349)
Property and equipment, net	$ 1,078	$ 1,031

Accrued expenses and other current liabilities consisted of the following (in thousands):

	JUNE 30, 2023	DECEMBER 31, 2022
Accrued compensation	$ 2,246	$ 3,544
Accrued research and development expenses	2,249	1,818
Accrued clinical expenses	2,156	438
Accrued professional services	1,048	313
Income tax and VAT payable	176	174
Accrued other liabilities	1,366	454
Total accrued expenses and other current liabilities	$ 9,241	$ 6,741

4. Fair Value Measurements

The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy which establishes three levels of inputs that may be used to measure fair value, as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities;

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

STRUCTURE THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

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

	JUNE 30, 2023				DECEMBER 31, 2022			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Money market funds	$ 25,592	$ —	$ —	$ 25,592	$ 18,994	$ —	$ —	$ 18,994
Commercial paper	—	9,975	—	9,975	—	—	—	—
Cash equivalents	25,592	9,975	—	35,567	18,994	—	—	18,994
U.S. government bonds	43,269	—	—	43,269	11,763	—	—	11,763
U.S. government agency bonds	—	33,846	—	33,846	—	1,794	—	1,794
Corporate debt securities	—	106,881	—	106,881	—	51,193	—	51,193
Short-term investments	43,269	140,727	—	183,996	11,763	52,987	—	64,750
Total fair value of financial assets	$ 68,861	$ 150,702	$ —	$ 219,563	$ 30,757	$ 52,987	$ —	$ 83,744

	JUNE 30, 2023				DECEMBER 31, 2022			
	AMORTIZED COST	GROSS UNREALIZED LOSSES	GROSS UNREALIZED GAINS	FAIR VALUE	AMORTIZED COST	GROSS UNREALIZED LOSSES	GROSS UNREALIZED GAINS	FAIR VALUE
Money market funds	$ 25,592	$ —	$ —	$ 25,592	$ 18,994	$ —	$ —	$ 18,994
Commercial paper	9,970	—	5	9,975	—	—	—	—
Cash equivalents	35,562	—	5	35,567	18,994	—	—	18,994
U.S. government bonds	43,433	(164)	—	43,269	11,820	(57)	—	11,763
U.S. government agency bonds	33,914	(77)	9	33,846	1,801	(7)	—	1,794
Corporate debt securities	107,044	(166)	3	106,881	51,239	(49)	3	51,193
Short-term investments	184,391	(407)	12	183,996	64,860	(113)	3	64,750
Total fair value of financial assets	$ 219,953	$ (407)	$ 17	$ 219,563	$ 83,854	$ (113)	$ 3	$ 83,744

As of June 30, 2023 and December 31, 2022, the Company did not have any liabilities measured at fair value on a recurring basis. There were no transfers in and out of Level 3 during the three and six months ended June 30, 2023 and 2022.

The unrealized losses for marketable securities related to changes in interest rates and the Company has the intent and ability to hold the underlying securities until the estimated date of recovery of its amortized cost. No allowance for credit losses was recorded as of June 30, 2023 and December 31, 2022, and no impairment losses were recognized for the three and six months ended June 30, 2023 and 2022.

5. Commitments and Contingencies

Operating Leases

The maturities of operating lease liabilities as of June 30, 2023, were as follows (in thousands):

	JUNE 30, 2023
2023	$ 74
Total undiscounted lease payments	74
Less: imputed interest	1
Total operating lease liability	73
Less: current portion	73
Operating lease liability, net of current portion	$ —

Operating lease cost was $0.3 million and $0.3 million for the three months ended June 30, 2023 and 2022, respectively, including $0.2 million and $0.2 million short-term lease costs for the three months ended June 30, 2023 and 2022, respectively. Operating lease cost was $0.6 million and $0.6 million for the six months ended June 30, 2023 and 2022, respectively, including $0.4 million and $0.4 million short-term lease costs for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, the weighted average remaining lease term was 0.3 years, and the weighted average discount rate used to measure the lease liabilities for such operating leases upon recognition was 7.4%. During the six months ended June 30, 2023 and 2022, cash paid for amounts included in operating lease liabilities of $0.2 million and $0.2 million, respectively, was included in cash flows from operating activities on the condensed consolidated statements of cash flows.

In June 2023, Shanghai ShouTi Biotechnology Co., Ltd. (“Shanghai ShouTi”), the Company’s wholly owned subsidiary, entered into a lease agreement for approximately 22,500 square feet of office space in Shanghai, China, for its research and development operations office. The commencement date is expected to be January 1, 2024 and will expire on December 31, 2026. The annual base rent will be approximately $0.7 million based on the exchange rate as of June 30, 2023, and it will also be responsible for the payment of additional costs and fees related to its use of the premises. As of June 30, 2023, Shanghai ShouTi has not taken possession of the premises.

In June 2023, Shanghai ShouTi entered into another lease agreement for approximately 8,400 square feet of laboratory space located in Shanghai, China for its research and development activities. The commencement date is expected to be February 1, 2024 and will expire on January 31, 2027. The annual base rent will be approximately $0.3 million based on the exchange rate as of June 30, 2023, and it will also be responsible for the payment of additional costs and fees related to its use of the premises. As of June 30, 2023, Shanghai ShouTi has not taken possession of the premises.

In June 2023, Structure Therapeutics USA Inc. (“Structure USA”), the Company’s wholly owned subsidiary, entered into a sublease agreement for approximately 11,800 square feet of office space located in South San Francisco, California for its corporate headquarters. The commencement date is expected to be August 1, 2023 and will expire on August 31, 2027. The annual base rent will initially be approximately $0.5 million and will increase annually by 3%, and it will also be responsible for the payment of additional costs and fees related to its use of the premises. As of June 30, 2023, Structure USA has not taken possession of the premises.

Indemnification Agreements

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential number of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by the applicable law and the amended and restated memorandum and articles of association of the Company. The Company currently has directors' and officers' liability insurance. As of June 30, 2023 and December 31, 2022, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently had not recorded related liabilities.

Legal Proceedings

The Company is subject to claims and assessments from time to time in the ordinary course of business but is not aware of any such matters, individually or in the aggregate, that will have a material adverse effect on the Company's financial position, results of operations or cash flows.

6. Redeemable Convertible Preferred Shares

Under the Company's Memorandum and Articles of Association, as amended, prior to the IPO, the Company's redeemable convertible preferred shares were issuable in series.

As of December 31, 2022, redeemable convertible preferred shares consisted of the following (in thousands, except share and per share amounts):

	DECEMBER 31, 2022				
SERIES	SHARES AUTHORIZED	ORIGINAL ISSUE PRICE	SHARES ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE
A	19,200,000	$ 1.6667	19,200,000	$ 32,001	$ 32,001
A+	12,799,681	2.0313	12,799,681	26,000	26,000
B	32,857,004	4.0483	32,857,004	133,015	133,015
B-1	2,161,402	3.2386	2,161,402	8,959	7,000
	67,018,087		67,018,087	$ 199,975	$ 198,016

Dividends on redeemable convertible preferred shares are noncumulative and none were declared through conversion. Upon closing of the Company's IPO, all outstanding redeemable convertible preferred shares automatically converted into 67,018,087 ordinary shares on a one-for-one basis.

7. Shareholders' Equity

As of June 30, 2023, the Company's Memorandum and Articles of Association, as amended, authorizes the Company to issue 500,000,000 ordinary shares and 100,000,000 undesignated shares, of which 7,410,518 shares have been designated as non-voting ordinary shares and 92,589,482 remain undesignated shares, all

with a par value of $0.0001 per share. The undesignated shares may be designated by the Company's board of directors in accordance with the Company's Articles of Association.

In May 2023, the Company's board of directors designated 7,410,518 non-voting ordinary shares in accordance with the Articles of Association. The non-voting ordinary shares rank on parity with the ordinary shares as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntary or involuntary. The non-voting ordinary shares are entitled on an equal basis to any dividends declared on the ordinary shares on an as-converted to ordinary share basis. Each non-voting ordinary shareholder has the right to convert each non-voting ordinary share into one ordinary share, subject to appropriate adjustment in the event of any dividend, split, reverse split, combination or other similar recapitalization with respect to the ordinary shares, at such holder's election by providing written notice to the Company, provided that such non-voting ordinary shares may only be converted into ordinary shares during such time or times as immediately prior to or as a result of such conversion would not result in the holder thereof beneficially owning, when aggregated with affiliates with whom such holder is required to aggregate beneficial ownership for purposes of Section 13(d) of the Exchange Act, in excess of the 9.99% of the ordinary shares (The "Beneficial Ownership Limitation"). Any non-voting ordinary shareholder may increase the Beneficial Ownership Limitation with respect to such holder, not to exceed 19.99% of the ordinary shares, upon 61 days' prior written notice to the Company and may decrease the Beneficial Ownership Limitation at any time upon providing written notice of such election to the Company; provided, however, that no holder may make such an election to change the percentage with respect to such holder unless all holders managed by the same investment advisor as such electing holder make the same election.

In May 2023, the Company entered into an Exchange Agreement with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., and Biotechnology Value Trading Fund OS, L.P. (each an "Investor" and together, the "Investors"), who in the aggregate hold more than 5% of the Company's issued share capital, pursuant to which the Investors delivered to the Company, a total of 7,410,518 ordinary shares of the Company, in exchange for the Company's delivery of 7,410,518 newly designated non-voting ordinary shares, par value $0.0001 per share. The exchange did not result in any change in the aggregate number of outstanding shares of the Company as the exchange was implemented on a one-for-one basis.

Ordinary shareholders, including non-voting ordinary shareholders, are entitled to dividends if and when declared by the Company's board of directors subject to the prior rights of any preferred shareholders. As of June 30, 2023 and December 31, 2022, no dividends on ordinary shares had been declared by the board of directors.

STRUCTURE THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Options

A summary of share option activity is set forth below (in thousands except per share amounts and years):

	NUMBER OF SHARES AVAILABLE FOR GRANT	OUTSTANDING AWARDS			
		NUMBER OF SHARES UNDERLYING OUTSTANDING OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE
As of December 31, 2022	977	7,612	$ 1.62	8.57	$ 13,283
Additional shares authorized	12,000	—	—		
Granted	(4,760)	4,760	5.79		
Exercised	—	(94)	2.22		
Forfeited	236	(236)	2.83		
As of June 30, 2023	8,453	12,042	3.24	8.67	127,869
Exercisable at June 30, 2023		3,248	1.23	7.71	41,028
Vested and expected to vest at June 30, 2023		12,042	3.24	8.67	127,869

The total fair value of options that vested during the three months ended June 30, 2023 and 2022 was $0.5 million and $0.6 million, respectively. The total fair value of options that vested during the six months ended June 30, 2023 and 2022 was $1.7 million and $0.7 million, respectively.

Restricted Shares

Activity with respect to restricted shares was as follows (in thousands, except per share amounts):

	NUMBER OF SHARES UNDERLYING OUTSTANDING RESTRICTED SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE
Unvested, December 31, 2022	327	$ 0.33
Vested	(327)	0.33
Unvested, June 30, 2023	—	—

The fair value of restricted shares vested during the three months ended June 30, 2023 and 2022 was less than $0.1 million and $0.1 million, respectively. The fair value of restricted shares vested during the six months ended June 30, 2023 and 2022 was $0.1 million and $0.2 million, respectively.

STRUCTURE THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Share-Based Compensation Associated with Awards to Employees and Non-Employees

The Company recognized share-based compensation as follows (in thousands):

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2023	2022 NOT REVIEWED	2023	2022 NOT REVIEWED
Research and development	$ 584	$ 232	$ 2,176	$ 491
General and administrative	1,118	411	2,059	772
Total share-based compensation	$ 1,702	$ 643	$ 4,235	$ 1,263

As of June 30, 2023, the total unrecognized share-based compensation expense related to unvested share options was $28.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 3.4 years.

China Employees' Options

The Company has granted share options to employees based in China. The exercise of share options granted to such employees was conditioned on a liquidity event, such as an IPO or change in control, which was not considered probable until consummated. The liquidity event condition was satisfied upon the closing of the IPO, and the Company recognized cumulative share-based compensation expense for share options granted to employees based in China. For the three and six months ended June 30, 2023, the Company recognized $0.2 million and $1.7 million in share-based compensation expense related to share options granted to employees based in China, respectively.

Performance Options

In February 2023, the Company's board of directors approved the grant of performance share options for 1,200,000 ordinary shares, which were granted under the 2023 Equity Incentive Plan. Each share option will vest over four years, subject to the achievement of certain clinical milestones as determined by the Company's compensation committee in the first year following the grant, and subject to the employees' continuous service through each vesting date. The achievement of performance milestones was not probable as of June 30, 2023. As such, no share-based compensation expense has been recognized for performance share options during the six months ended June 30, 2023.

Ordinary Share Warrants

In connection with entering into a Loan and Security Agreement (the "SVB Agreement") with Silicon Valley Bank ("SVB"), the Company issued SVB a warrant to purchase shares of its ordinary shares at an exercise price of $0.48 per share ("SVB Warrant"). The SVB Warrant was immediately exercisable for 112,279 ordinary shares of the Company and could have been exercisable for an additional number of ordinary shares equal to 44,567 ordinary shares upon draw of Tranche A under the SVB Agreement and 22,283 ordinary shares upon draw of Tranche B under the SVB Agreement. The warrant for Tranche A shares and Tranche B shares expired on July 31, 2021 and July 31, 2022, respectively, as the Company elected to allow the Tranche A and Tranche B financings to expire unused on July 31, 2021 and July 31, 2022, respectively. In February 2023, SVB fully exercised the SVB Warrant for 106,060 ordinary shares through a cashless exercise.

STRUCTURE THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

8. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share attributable to ordinary shareholders, which excludes unvested restricted shares and shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except per share amounts):

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2023	2022 NOT REVIEWED	2023	2022 NOT REVIEWED
Numerator:				
Net loss attributable to ordinary shareholders	$ (23,280)	$ (13,948)	$ (41,255)	$ (27,029)
Accretion of redeemable convertible preferred shares to their redemption value	—	(1,515)	—	(1,515)
Net loss attributable to ordinary shareholders	$ (23,280)	$ (15,463)	$ (41,255)	$ (28,544)
Denominator:				
Weighted-average ordinary shares outstanding	114,784	10,899	93,457	10,897
Less: weighted-average unvested restricted ordinary shares subject to repurchase	(25)	(1,464)	(132)	(1,647)
Weighted-average ordinary shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	114,759	9,435	93,325	9,250
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (0.20)	$ (1.64)	$ (0.44)	$ (3.09)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to ordinary shareholders for the periods presented because including them would have been antidilutive (in thousands):

	AS OF JUNE 30,	
	2023	2022 NOT REVIEWED
Redeemable convertible preferred shares	—	67,018
Options to purchase ordinary shares	12,042	7,356
Ordinary share warrants	—	135
Unvested restricted ordinary share awards	—	818
Total	12,042	75,327

9. Related Party Transactions

Ramy Farid, the President and Chief Executive Officer of Schrödinger, Inc. (“Schrödinger”) is a member of the Company’s board of directors. During the three and six months ended June 30, 2023 and 2022, the Company had existing collaboration agreements to use the results provided by Schrödinger’s software platform for its research purposes. During the three months ended June 30, 2023 and 2022, the Company paid $0 and less

than $0.1 million to Schrödinger, respectively. During the six months ended June 30, 2023 and 2022, the Company paid $0 and $0.2 million to Schrödinger, respectively, and had no payable balance to Schrödinger as of June 30, 2023 and December 31, 2022.

Lhotse Collaboration Agreement with Schrödinger

In In October 2020, Lhotse Bio, Inc., the Company's wholly-owned subsidiary, entered into a Collaboration Agreement (the "Lhotse-Schrödinger Agreement") with Schrödinger to discover and develop novel, orally bioavailable, small molecule inhibitors of LPA1R. Under the Lhotse-Schrödinger Agreement, Schrödinger is obligated to provide computational modeling and design support, including by using its technology platform to perform virtual screens, and Lhotse is obligated to provide day-to-day chemistry and biology support. Pursuant to the Lhotse-Schrödinger Agreement, a joint steering committee comprised of representatives from both parties oversees the research performed under the agreement. During the term of the Lhotse-Schrödinger Agreement and for a specified period thereafter while Lhotse is engaged in active development of any compound having activity against LPA1R that is discovered or developed under the Lhotse-Schrödinger Agreement, Schrödinger is obligated to work exclusively with Lhotse on the design, research, development and commercialization of compounds that inhibit LPA1R. Lhotse will solely own the research results, work product, inventions and other intellectual property generated under the Lhotse-Schrödinger Agreement that are directed to LPA1R.

Under the Lhotse-Schrödinger Agreement, Lhotse is obligated to pay Schrödinger a quarterly active program payment in the low six digits for each successive three-month period during which Schrödinger continues to perform research work as agreed by the parties, and as of June 30, 2023, the Company has paid to Schrödinger an aggregate of $0.8 million. If Lhotse develops and commercializes a product containing a compound (a "Collaboration Compound"), that is discovered or developed under the Lhotse-Schrödinger Agreement (a "Collaboration Product"), Lhotse is obligated to pay Schrödinger development and regulatory milestone payments of up to an aggregate of $17.0 million, regardless of the number of Collaboration Products that reach such milestones. Lhotse will also be obligated to pay Schrödinger tiered royalties on a Collaboration Product-by-Collaboration Product basis equal to low single digit percentages on aggregate worldwide net sales of Collaboration Products, subject to specified reductions and offsets. Lhotse's obligation to pay royalties to Schrödinger will expire on a Collaboration Product-by-Collaboration Product and country-by-country basis on the later of (i) the expiration of the last-to-expire Lhotse patent claim covering the composition of matter of the Collaboration Compound contained in such Collaboration Product in such country, (ii) the expiration of regulatory, pediatric, orphan drug, or data exclusivity with respect to such Collaboration Product in such country, and (iii) ten years after the first commercial sale of such Collaboration Product in such country (the "Royalty Term").

Unless terminated earlier, the Lhotse-Schrödinger Agreement will continue for three years, subject to extension by mutual written agreement of the parties. Either party may terminate the Lhotse-Schrödinger Agreement for the other party's uncured material breach, subject to certain notice and cure periods, or for the other party's bankruptcy or insolvency. Lhotse's obligation to make milestone and royalty payments (subject to the Royalty Term) to Schrödinger continues after the expiration or termination of the Lhotse-Schrödinger Agreement. As of June 30, 2023, no milestone or royalty payments have been paid or accrued.

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

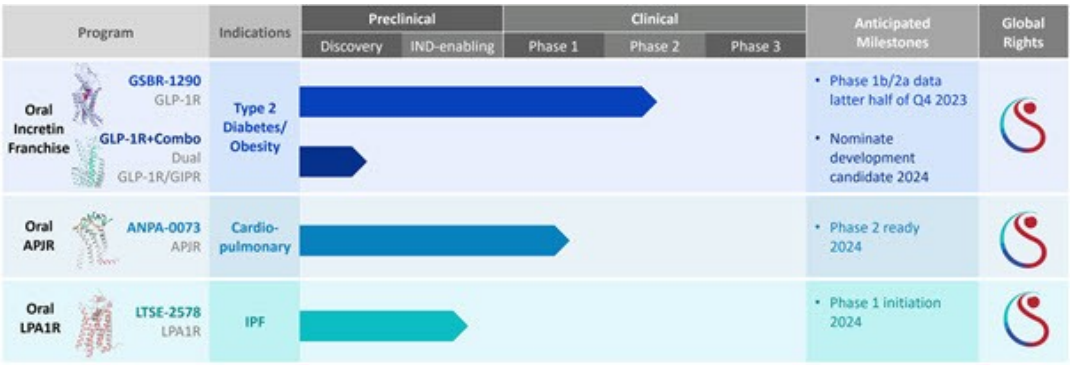
You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections of this Quarterly Report entitled "Forward-Looking Statements" and "Risk Factors," under Part II. Item 1A. and those discussed in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission ("SEC") on March 30, 2023.

Overview

We are a clinical stage global biopharmaceutical company aiming to develop and deliver novel oral therapeutics to treat a wide range of chronic diseases with unmet medical need. Our differentiated technology platform leverages structure-based drug discovery and computational chemistry expertise and enables us to develop oral small molecule therapeutics for the treatment of various diseases including those impacting the metabolic, cardiovascular, and pulmonary systems. In February 2023, we completed our Initial Public Offering ("IPO") for net proceeds of $166.7 million.

Our initial focus is on G-protein coupled receptors ("GPCRs") as a therapeutic target class. GPCRs regulate numerous diverse physiological and pathological processes, and approximately one in every three marketed medicines targets GPCR-associated pathways. By leveraging our world-class GPCR know-how, we aim to design differentiated small molecule therapies to overcome the limitations of biologics and peptide therapies targeting this family of receptors. We are developing GSBR-1290, our oral small molecule product candidate targeting the validated GLP-1R for the treatment of type 2 diabetes mellitus ("T2DM") and obesity. We completed our Phase 1 single ascending dose ("SAD") study of GSBR-1290 in September 2022. GSBR-1290 was generally well tolerated and demonstrated dose-dependent pharmacokinetic ("PK") and pharmacodynamic ("PD") activity. We submitted an investigational new drug ("IND") application to the U.S. Food and Drug Administration ("FDA") to support initiation of a Phase 1b study in T2DM and obesity and received FDA allowance in September 2022. We initiated the Phase 1b multiple ascending dose ("MAD") study in January 2023 and completed dosing in healthy overweight subjects in March 2023. We submitted a protocol amendment to the FDA and transitioned to a Phase 2a proof-of-concept study in T2DM and obesity. We also initiated the dosing of the Phase 2a study in May 2023 and recently completed enrollment. We expect to report topline data for the Phase 1b MAD study and Phase 2a study in the latter half of the fourth quarter of 2023. We also completed an ethnobridging study of GSBR-1290 in Japanese individuals and are planning to initiate an additional formulation bridging study to evaluate a tablet formulation of GSBR-1290 before the end of 2023, both in preparation for the planned global Phase 2b study in 2024. Beyond GSBR-1290, we are developing next generation combination GLP-1R candidates, including dual GLP-1R/GIPR agonists and amylin agonists, each designed with customized properties to achieve additional benefits. In September 2022, we completed a Phase 1 SAD and MAD study evaluating ANPA-0073, our small molecule product candidate targeting APJR. ANPA-0073 was generally well tolerated in healthy human volunteers. ANPA-0073 is in development for the treatment of patients with idiopathic pulmonary fibrosis ("IPF") and pulmonary arterial hypertension ("PAH"). We expect to conduct additional preclinical studies to be followed by a Phase 1 formulation bridging PK study in Australia. Moreover, we are advancing a differentiated lysophosphatidic acid 1 receptor ("LPA1R") antagonist for the treatment of IPF. We selected a development candidate in January 2023 and expect to initiate a first-in-human study in 2024.

We are advancing a robust pipeline of small molecule therapeutic candidates for chronic diseases with unmet medical need.



We outsource clinical drug manufacturing, storage, distribution and quality testing to third-party manufacturers. We believe this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the design and development of our product candidates. As our development programs progress and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying demand for registration trials and, if approved, the manufacture, sale and distribution of commercial products.

We are a Cayman Islands exempted company incorporated with limited liability. We were initially formed as a Delaware limited liability company in 2016 under the name ShouTi Inc., and reorganized as a Cayman Islands exempted company in February 2019. Our primary activities to date have included organizing and staffing our company, business and scientific planning, raising capital, conducting research and development activities, entering into strategic and corporate structuring transactions, enabling manufacturing activities in support of our product candidate development efforts, and establishing our intellectual property portfolio, and providing general and administrative support for these activities. We do not have any product candidates approved for sale and have not generated any revenue from our products. Since our inception, we have incurred net operating losses and negative cash flows from operations. We had net losses of $41.3 million and $27.0 million in the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $158.2 million. Historically, we have financed our operations primarily through the private placement of equity securities. On February 7, 2023, we completed our IPO of our American depositary shares (“ADSs”), in which we issued and sold an aggregate of 12,351,000 ADSs (inclusive of 1,611,000 ADSs pursuant to the exercise by the underwriters of their option) at a price of $15.00 per ADS for net cash proceeds of approximately $166.7 million, net of underwriting discounts and commissions and estimated offering costs. Upon the closing of the IPO, all outstanding shares of redeemable convertible preferred shares automatically converted into 67,018,087 ordinary shares. Subsequent to the closing of the IPO, there were no shares of redeemable convertible preferred shares outstanding.

As of June 30, 2023, we have cash, cash equivalents and short-term investments of $224.6 million. Based on our current business plan, we estimate that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations through at least 2025. We have based this estimate on assumptions that may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, particularly if and as we continue to invest in our research and development activities and initiate additional clinical trials, expand our product pipeline, hire additional personnel and invest in and grow our

business, maintain, expand and protect our intellectual property portfolio, and seek regulatory approvals for and commercialize any approved product candidates. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory, consulting, and tax-related services associated with being a public company, compliance with Nasdaq listing and SEC requirements, director and officer insurance premiums and investor relations costs that we did not incur as a private company. As a result, we will need substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Moreover, we may in the future seek to acquire or invest in additional businesses, products, or technologies that we believe could complement or enhance our product, enhance our technical capabilities or otherwise offer growth opportunities, although we currently have no agreements or understandings with respect to any such acquisitions or investments. Until such time as we can generate significant revenue from our products, if ever, we expect to finance our operations through the public or private sale of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. If we are unable to obtain additional funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or any commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. If we raise funds through strategic collaborations or other similar arrangements with third-parties, we may have to relinquish valuable rights to our platform technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our ordinary shares. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from rising interest rates, future bank failures, global pandemics, the Russia/Ukraine conflict or other events. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

Impact of Geopolitical and Macroeconomic Factors

Although we did not see a significant financial impact to our business operations as a result of recent geopolitical and macroeconomic developments, such as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, global pandemics, geopolitical tensions between the U.S. and China and the ongoing Russia/Ukraine conflict for the six months ended June 30, 2023, there may be potential impacts to our business in the future that are highly uncertain and difficult to predict, including disruptions to the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research, preclinical studies and clinical trials, impediments to our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, delays in the FDA's review and approval processes, our ability to effectively operate across different geographies in which our offices are located, continued increases in interest rates and economic inflation, bank failures, higher prices of supplies, and changes in availability and cost of credit and our ability to access capital. The ultimate impact of these geopolitical and macroeconomic factors, as well as any lasting effects on the way we conduct our business, is highly uncertain and subject to continued change, and we recognize that they may continue to present unique challenges for us.

Lhotse Collaboration Agreement with Schrödinger, LLC

In October 2020, Lhotse Bio, Inc., our wholly-owned subsidiary, entered into a Collaboration Agreement (the "Lhotse-Schrödinger Agreement") with Schrödinger, LLC ("Schrödinger") to discover and develop novel, orally bioavailable, small molecule inhibitors of LPA1R. Under the Lhotse-Schrödinger Agreement, Schrödinger is obligated to provide computational modeling and design support, including by using its technology platform to perform virtual screens, and Lhotse is obligated to provide day-to-day chemistry and biology support. Pursuant to the Lhotse-Schrödinger Agreement, a joint steering committee comprised of representatives from both parties oversees the research performed under the agreement. During the term of the Lhotse-Schrödinger Agreement and for a specified period thereafter while Lhotse is engaged in active development

of any compound having activity against LPA1R that is discovered or developed under the Lhotse-Schrödinger Agreement, Schrödinger is obligated to work exclusively with Lhotse on the design, research, development and commercialization of compounds that inhibit LPA1R. Lhotse will solely own the research results, work product, inventions and other intellectual property generated under the Lhotse-Schrödinger Agreement that are directed to LPA1R.

Under the Lhotse-Schrödinger Agreement, Lhotse is obligated to pay Schrödinger a quarterly active program payment in the low six digits for each successive three-month period during which Schrödinger continues to perform research work as agreed by the parties, and as of June 30, 2023, we have paid to Schrödinger an aggregate of $0.8 million. If Lhotse develops and commercializes a product containing a compound (a "Collaboration Compound"), that is discovered or developed under the Lhotse-Schrödinger Agreement (a "Collaboration Product"), Lhotse is obligated to pay Schrödinger development and regulatory milestone payments of up to an aggregate of $17.0 million, regardless of the number of Collaboration Products that reach such milestones. Lhotse will also be obligated to pay Schrödinger tiered royalties on a Collaboration Product-by-Collaboration Product basis equal to low single digit percentages on aggregate worldwide net sales of Collaboration Products, subject to specified reductions and offsets. Lhotse's obligation to pay royalties to Schrödinger will expire on a Collaboration Product-by-Collaboration Product and country-by-country basis on the later of (i) the expiration of the last-to-expire Lhotse patent claim covering the composition of matter of the Collaboration Compound contained in such Collaboration Product in such country, (ii) the expiration of regulatory, pediatric, orphan drug, or data exclusivity with respect to such Collaboration Product in such country, and (iii) ten years after the first commercial sale of such Collaboration Product in such country (the "Royalty Term").

Unless terminated earlier, the Lhotse-Schrödinger Agreement will continue for three years, subject to extension by mutual written agreement of the parties. Either party may terminate the Lhotse-Schrödinger Agreement for the other party's uncured material breach, subject to certain notice and cure periods, or for the other party's bankruptcy or insolvency. Lhotse's obligation to make milestone and royalty payments (subject to the Royalty Term) to Schrödinger continues after the expiration or termination of the Lhotse-Schrödinger Agreement. As of June 30, 2023, no milestone or royalty payments have been paid or accrued.

Components of Our Results of Operations

Operating Expenses

Research and Development

Our research and development activities primarily consist of discovery, engineering and research associated with our product candidates under development, including preclinical studies and clinical studies. Research and development expenses include personnel-related costs for our management, including salaries, bonuses, benefits and share-based compensation expenses, consulting services, clinical trial expenses, regulatory expenses, publications, and allocated overhead expenses, including rent, equipment, depreciation, information technology costs and utilities.

We are focusing substantially all of our resources on the development of our product candidates and the discovery of new product candidates through our structure-based drug discovery platform. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of our clinical trials and preclinical studies and other research and development activities;
- the phases of development of our product candidates;

- the number of trials required for approval;
- the number of sites included in our trials;
- the countries in which our trials are conducted;
- per subject trial costs;
- uncertainties in clinical trial enrollment rates or design and drop-out/discontinuation rates;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals;
- the FDA's, or other regulatory authority's influence on clinical trial design;
- making arrangements with third-party contract research organizations ("CROs");
- the cost and timing of manufacturing our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; the extent to which we establish additional strategic arrangements;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; and
- retention of key research and development personnel.

A change in the outcome of any of these variables with respect to the development of a product candidate could significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA, or an applicable foreign authority, were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of our product candidates, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

We expect our research and development expenses to continue to account for a significant portion of our operating expenses, and to increase substantially during the next several years as we seek to complete preclinical studies, initiate and/or complete clinical trials, identify new product candidates and potentially pursue regulatory approval of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related costs for personnel in executive, legal, finance and other administrative functions, including salaries, bonuses, benefits and share-based compensation expenses, professional fees for legal, consulting, accounting and tax services, allocated overhead expenses, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We expect our general and administrative expenses will increase during the next several years as we increase our headcount and expand our infrastructure to support our operations, particularly as a public company. Additionally, in connection with being a public company, we anticipate significant increased expenses related to legal, audit, accounting, regulatory, consulting, and tax-related services, compliance with SEC rules and regulations and Nasdaq listing requirements, director and officer insurance premiums and investor relations costs. Our general and administrative expenses may fluctuate from period to period as we continue to grow.

Interest and Other Income (Expense), Net

Interest and other income (expense), net primarily consists of interest income earned on our cash, cash equivalents and short-term investments, including amortization and accretion of premiums and discounts on short-term investments, foreign currency exchange gains and losses and interest expense for the amortization of debt issuance costs.

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

The following table summarizes our consolidated results of operations for the periods indicated (in thousands):

	THREE MONTHS ENDED JUNE 30,	
	2023	2022
Operating expenses:		
Research and development	$ 19,411	$ 10,181
General and administrative	6,576	3,779
Total operating expenses	25,987	13,960
Loss from operations	(25,987)	(13,960)
Interest and other income (expense), net	2,825	76
Loss before income tax expense	(23,162)	(13,884)
Provision for income taxes	118	64
Net loss	$ (23,280)	$ (13,948)

Research and Development Expenses

Research and development expenses increased by $9.2 million, or 91%, to $19.4 million during the three months ended June 30, 2023, compared to $10.2 million during the three months ended June 30, 2022. The increase in research and development expenses was primarily due to the advancement of our GLP-1R franchise and other research programs and increases related to employee expenses, primarily due to an increase in personnel.

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	THREE MONTHS ENDED JUNE 30,	
	2023	2022
Product candidate:		
ANPA-0073	$ 1,865	$ 1,276
GSBR-1290	13,411	5,326
LTSE-2578	1,453	1,488
Other	2,682	2,091
Total research and development expenses	$ 19,411	$ 10,181

General and Administrative Expenses

General and administrative expenses increased by $2.8 million, or 74%, to $6.6 million during the three months ended June 30, 2023, compared to $3.8 million during the three months ended June 30, 2022. The increase in general and administrative expenses was primarily due to increases in professional services and employee related expenses as we expanded our infrastructure to drive and support the growth in our operations as a publicly-traded company.

Interest and Other Income (Expense), Net

Interest and other income (expense), net, increased by $2.7 million to an income of $2.8 million during the three months ended June 30, 2023, compared to an income of $0.1 million during the three months ended June 30, 2022. The increase in interest and other income (expense), net, was primarily due to an increase in interest income from higher interest rates and cash, cash equivalents and short-term investment balances.

Comparison of the Six Months Ended June 30, 2023 and 2022

The following table summarizes our consolidated results of operations for the periods indicated (in thousands):

	SIX MONTHS ENDED JUNE 30,	
	2023	2022
Operating expenses:		
Research and development	$ 32,546	$ 18,673
General and administrative	13,090	8,239
Total operating expenses	45,636	26,912
Loss from operations	(45,636)	(26,912)
Interest and other income (expense), net	4,524	7
Loss before provision for income taxes	(41,112)	(26,905)
Provision for income taxes	143	124
Net loss	$ (41,255)	$ (27,029)

Research and Development Expenses

Research and development expenses increased by $13.9 million, or 74%, to $32.5 million during the six months ended June 30, 2023, compared to $18.7 million during the six months ended June 30, 2022. The

increase in research and development expenses was primarily due to the advancement of our GLP-1R franchise and other research programs and increases related to employee expenses, primarily due an increase in personnel.

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	SIX MONTHS ENDED JUNE 30,	
	2023	2022
Product candidate:		
ANPA-0073	$ 2,413	$ 3,306
GSBR-1290	21,282	8,576
LTSE-2578	2,375	2,471
Other	6,476	4,320
Total research and development expenses	$ 32,546	$ 18,673

General and Administrative Expenses

General and administrative expenses increased by $4.9 million, or 59%, to $13.1 million during the six months ended June 30, 2023, compared to $8.2 million during the six months ended June 30, 2022. The increase in general and administrative expenses was primarily due to increases in professional services and employee related expenses and professional services as we expanded our infrastructure to drive and support the growth in our operations as a publicly-traded company.

Interest and Other Income (Expense), Net

Interest and other income (expense), net, increased by $4.5 million to an income of $4.5 million during the six months ended June 30, 2023, compared to an income of less than $0.1 million during the six months ended June 30, 2022. The increase in interest and other income (expense), net, was primarily due to an increase in interest income from higher interest rates and cash, cash equivalents and short-term investment balances.

Liquidity and Capital Resources

From our reorganization as a Cayman Islands exempted company in February 2019 through immediately prior to completion of our IPO, we funded our operations primarily with an aggregate of $198.0 million in gross cash proceeds from the sale of redeemable convertible preferred shares. On February 7, 2023, we completed our IPO and received $166.7 million in net proceeds after deducting underwriting discounts and commissions and estimated offering costs. As of June 30, 2023, we had cash, cash equivalents and short-term investments of $224.6 million and an accumulated deficit of $158.2 million.

Redeemable Convertible Preferred Shares

Series A Redeemable Convertible Preferred Shares

In April 2019, we entered into a Series A redeemable convertible preferred shares purchase agreement (the “Series A Purchase Agreement”), with certain investors to issue and sell 9,600,000 shares of Series A redeemable convertible preferred shares at $1.6667 per share (the “Series A Purchase Price”), for total gross proceeds of $16.0 million.

The Series A Purchase Agreement also provided for the issuance and sale to the investors of an additional 9,600,000 shares of Series A redeemable convertible preferred shares at the Series A Purchase Price upon achieving certain milestone conditions (the “Series A Milestone Closing”).

The issuance of Series A redeemable convertible preferred shares was recorded at the amount of proceeds received less issuance costs and the amounts allocated to the Series A Milestone Closing liability.

The Series A Milestone Closing occurred on December 9, 2019, and we issued 9,600,000 shares of Series A redeemable convertible preferred shares at the Series A Purchase Price for gross proceeds of $16.0 million.

Series A+ Redeemable Convertible Preferred Shares

In March 2020, we entered into a Series A+ redeemable convertible preferred shares purchase agreement with certain investors to issue and sell 12,799,681 shares of Series A+ redeemable convertible preferred shares at $2.0313 per share, for total gross proceeds of $26.0 million.

Series B Redeemable Convertible Preferred Shares

In July 2021, we entered into a Series B redeemable convertible preferred shares purchase agreement with certain investors to issue and sell 24,701,732 shares of Series B redeemable convertible preferred shares at $4.0483 per share, for total gross proceeds of $100.0 million.

In April 2022, we issued an additional 8,155,272 shares of our Series B redeemable convertible preferred shares for total gross proceeds of $33.0 million, also at $4.0483 per share.

Series B-1 Redeemable Convertible Preferred Shares

In March 2021, Basecamp Bio, Inc. (“Basecamp Bio”), our wholly owned subsidiary incorporated in February 2021, entered into a purchase agreement with certain investors to issue and sell 9,000,000 shares of its Series Seed redeemable convertible preferred shares at a price of $1.00 per share for total gross proceeds of $9.0 million. Of the 9,000,000 shares of Series Seed redeemable convertible preferred shares issued, 2,000,000 shares were issued to us and the remaining 7,000,000 shares were issued to other existing investors in Structure Therapeutics.

In December 2021, we acquired the 7,000,000 Series Seed redeemable convertible preferred shares of Basecamp Bio held by the other investors in exchange for 2,161,402 shares of our Series B-1 redeemable convertible preferred stock, with Basecamp Bio becoming a wholly owned subsidiary again.

Upon the closing of our IPO, all outstanding shares of redeemable convertible preferred stock automatically converted into 67,018,087 ordinary shares.

Funding Requirements

Prior to our IPO, we financed our operations primarily through the private placement of equity securities and have received aggregate gross proceeds of approximately $198.0 million. Since our inception, we have incurred net operating losses and negative cash flows from operations. We had net losses of $41.3 million and $27.0 million in the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $158.2 million. In February 2023, we completed our IPO for net proceeds of $166.7 million. Our primary activities to date have included organizing and staffing our company, business and scientific planning, raising capital, conducting research and development activities, entering into strategic and corporate structuring transactions, enabling manufacturing activities in support of our product candidate development efforts, establishing our intellectual property portfolio, and providing general and administrative support for these activities.

As of June 30, 2023, we had cash, cash equivalents and short-term investments of $224.6 million. Based on our current business plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations for the next 12 months from the date of the issuance of our condensed consolidated financial statements. We have based this estimate on assumptions that may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

To date, we have not generated any revenue from our products. We do not expect to generate any significant product revenue until we successfully develop and obtain regulatory approval for and commercialize our product candidates, and we do not know when, or if, either will occur. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, particularly if and as we continue to invest in our research and development activities and initiate additional clinical trials, expand our product pipeline, hire additional personnel and invest in and grow our business, maintain, expand and protect our intellectual property portfolio, and seek regulatory approvals for and commercialize any approved product candidates. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory, tax-related, director and officer insurance, investor relations and other expenses that we did not incur as a private company. Moreover, we may in the future seek to acquire or invest in additional businesses, products, or technologies that we believe could complement or enhance our product, enhance our technical capabilities or otherwise offer growth opportunities, although we currently have no agreements or understandings with respect to any such acquisitions or investments. We are subject to the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We will need substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the scope, timing, rate of progress and costs of our preclinical development activities, laboratory testing and clinical trials for our product candidates;
- 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 of manufacturing our product candidates;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- 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 FDA approval;
- our implementation of operational, financial and management systems; and
- the impact of geopolitical and macroeconomic events, including future bank failures, increased geopolitical tensions between the U.S. and China, the Russia/Ukraine conflict and global pandemics on U.S. and global economic conditions that may impact our ability to access capital on acceptable terms, if at all.

A change in the outcome of any of these or other variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our business plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such plans.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a holder of our ADSs. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends, which could adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise funds through strategic collaborations or other similar arrangements with third-parties, we may have to relinquish valuable rights to our platform technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our ordinary shares.

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from geopolitical and macroeconomic events such as actual or anticipated changes in interest rates and economic inflation, current and future bank failures, global pandemics, geopolitical tensions between the U.S. and China and the impact of the Russia/Ukraine conflict. If we are unable to obtain additional funding, or funding on acceptable terms, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or any commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

Summary Statements of Cash Flows

The following table sets forth the primary sources and uses of cash for the periods presented below (in thousands):

	SIX MONTHS ENDED JUNE 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (37,202)	$ (23,613)
Investing activities	(117,727)	(55,792)
Financing activities	169,429	29,589
Net increase (decrease) in cash and cash equivalents	$ 14,500	$ (49,816)

Cash Flows Used in Operating Activities

During the six months ended June 30, 2023, net cash used in operating activities was $37.2 million, consisting primarily of a net loss of $41.3 million, partially offset by non-cash charges of $2.6 million and a decrease in net operating assets of $1.5 million. The cash used in operations was primarily due to the increase in net loss from the increase in operating expenses as we invest in our research and development

efforts and operate as a publicly-traded company. Non-cash charges consisted primarily of share-based compensation and accretion of net investment discount. The decrease in net operating assets was primarily due to an increase in accrued expenses and other current liabilities, partially offset by an increase in prepaid expenses and other current assets.

During the six months ended June 30, 2022, net cash used in operating activities was $23.6 million, consisting primarily of a net loss of $27.0 million, partly offset by a decrease in net operating assets of $2.0 million and non-cash charges of $1.4 million. The cash used in operations was primarily due to the increase in net loss from the increase in operating expenses as we invested in our research and development efforts and prepared to become a publicly-traded company. The decrease in net operating assets is primarily due to an increase in accrued expenses and other current liabilities, partially offset by an increase in prepaid expenses and other current assets. Non-cash charges consisted primarily of share-based compensation.

Cash Flows Used in Investing Activities

During the six months ended June 30, 2023, net cash used in investing activities was $117.7 million, consisting primarily of net purchases of short-term investments.

During the six months ended June 30, 2022, net cash used in investing activities was $55.8 million, consisting primarily of net purchases of short-term investments.

Cash Flows Provided by Financing Activities

During the six months ended June 30, 2023, net cash provided by financing activities was $169.4 million, consisting primarily of proceeds from our IPO of $172.3 million, net of underwriting discounts and commissions, partially offset by payment of deferred offering costs of $3.1 million.

During the six months ended June 30, 2022, net cash provided by financing activities was $29.6 million, consisting primarily of net proceeds from the issuance of our Series B redeemable convertible preferred shares of $31.5 million, partially offset by payments of deferred offering costs of $1.9 million.

Contractual Obligations

As of June 30, 2023, our contractual obligations consist of facilities lease payments totaling $0.1 million through October 31, 2023. In June 2023, the Company entered into three lease agreements which are expected to commence in August 2023, January 2024 and February 2024. See “Operating Leases” in Note 5 to our unaudited interim condensed consolidated financial statements for additional information.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”). The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our knowledge of current events and actions we may undertake in the future and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may materially differ from these estimates under different assumptions or conditions.

Our critical accounting policies and estimates are described in “Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Significant Judgments and

Estimates" in our Annual Report on Form 10-K filed with the SEC on March 30, 2023. There were no material changes to these accounting policies during the six months ended June 30, 2023.

JOBS Act Accounting Election and Smaller Reporting Company Status

We are an "emerging growth company," as defined in 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. We have elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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 and will be able to take advantage of these scaled disclosures for so long as our ordinary shares held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our ordinary shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

See "Recent Accounting Pronouncements" in Note 2 to our unaudited interim condensed consolidated financial statements included in Part I. Item 1 "Financial Statements" in this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined in Item 10 of Regulation S-K and are not required to provide the information otherwise required 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 our Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. These disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of June 30, 2023, our disclosure controls and procedures were not effective at the reasonable assurance level because of the material weaknesses in our internal control over financial reporting as described below.

Material Weaknesses in Internal Controls Over Financial Reporting

We previously identified the material weaknesses in our internal control over financial reporting that continues to exist as of June 30, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. These material weaknesses are as follows:

We did not design and maintain an effective control environment commensurate with our financial reporting requirements as we lacked a sufficient complement of professionals commensurate with our financial reporting requirements. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, amongst other things, insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses:

We did not design and maintain effective controls to ensure adequate segregation of duties within our financial reporting function, including controls related to the procurement and payroll processes, journal entries and account reconciliations. Specifically, certain personnel have incompatible duties including the ability to (i) generate and approve invoices and authorize disbursements; (ii) add employees or modify employee data in the payroll system and authorize payments; (iii) create and post manual journal entries without an independent review; and (iv) prepare and review account reconciliations.

We did not design and maintain effective controls over certain information technology (“IT”) general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that program and data changes are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel; and (iii) computer operations controls to ensure that processing of data and data backups and recovery are monitored.

These material weaknesses did not result in any material misstatements to the consolidated financial statements. These material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

Management's Plan to Remediate the Material Weaknesses

We have taken and will continue to take certain measures to remediate the material weaknesses described above.

We have begun to hire additional accounting and IT personnel, including but not limited to the hiring of a senior director of SEC reporting and technical reporting in December 2021, director of finance and financial planning and analysis in February 2022 and director of information security in April 2022. In May 2022, we appointed our existing chief operating officer as our chief financial officer. In addition to the key hires, we have also engaged third-party consultants and advisors to assist us in designing and implementing controls necessary to remediate the material weakness, including formalization of our control environment using the criteria described in "Internal Control - Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), implementing segregation of duties in the areas described above which gave rise to the material weaknesses and implementation of key mitigating controls to address key risks, and establishing key IT general controls over relevant IT domains and key systems relevant to our financial reporting processes. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. We are working to remediate the material weaknesses as efficiently and effectively as possible.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management's evaluation pursuant to Rules 13a-15(f) or 15d-15(f) of the Exchange Act during our second quarter ended June 30, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Disclosure Controls and Procedures

A system of internal control over financial reporting is intended to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP and no control system, no matter how well designed and operated, can provide absolute assurance. The design of any control system is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of its inherent limitations, internal control over financial reporting may not prevent or detect financial statement errors and misstatements. Also, projection of any evaluation of effectiveness to future periods is subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

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.

Item 1A. Risk Factors.

Investing in our ADSs, involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report, including our consolidated financial statements and their related notes included in Part I. Item 1 "Financial Statements" of this Quarterly Report and Part I. Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" before making an investment decision. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our ADSs could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results and financial condition.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history and have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Since our inception in 2016, we have focused primarily on organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, developing our structure-based drug discovery platform, identifying and developing our product candidates, conducting preclinical studies and, more recently, clinical trials, and providing general and administrative support for these operations. Our approach to the discovery and development of product candidates based on our structure-based drug discovery platform is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or commercially. Further, GSBR-1290, our product candidate for T2DM and obesity, and ANPA-0073, our product candidate for IPF and PAH, are in early clinical development and our other product candidates and programs are in preclinical development or discovery stages. Accordingly, we have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses since our inception and expect to continue to incur significant and increasing operating losses for at least the next several years. Our net losses were $41.3 million and $51.3 million for the six months ended June 30, 2023 and year ended December 31, 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $158.2 million. Substantially all of

our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. In February 2023, we completed our IPO, for net proceeds of $166.7 million. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive marketing approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate that our expenses will increase substantially as we continue our development of, seek marketing approval for and potentially commercialize any of our product candidates, recruit and maintain key personnel and seek to identify, assess, acquire, in-license or develop additional product candidates.

Even if we succeed in developing and obtaining marketing approval for one or more product candidates, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable could decrease the value of our ADSs and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials of GSBR-1290, ANPA-0073, LTSE-2578 and any future product candidates we may develop. Our expenses will increase substantially if our product candidates successfully complete early clinical and other studies, and also could increase beyond expectations if the FDA or foreign authorities require us to perform clinical and other studies in addition to those that we currently anticipate. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company. Furthermore, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based on our current operating plan, we believe that our cash, cash equivalents and short-term investments as of June 30, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements through at least 2025. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses and other similar arrangements. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and, if approved, commercialize our current and any future product candidates. Additional funding may not be available on acceptable terms, or at all. As a result of actual or anticipated changes in interest rates and economic inflation and the impact of the Russia/Ukraine conflict, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth,

increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, including as a result of recent or future bank failures, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

Our future funding requirements will depend on many factors, including:

- the progress, costs, design, results of and timing of our planned and ongoing preclinical studies and clinical trials;
- the willingness of the FDA or applicable foreign authorities to accept our clinical trials, as well as data from our planned and ongoing preclinical studies and clinical trials and other work, as the basis for review and approval of our product candidates;
- the outcome, costs and timing of seeking and obtaining FDA and applicable foreign regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our need to expand our research and development capabilities, including further development of our structure-based drug discovery platform or in-licensing of complementary technologies;
- the costs and timing associated with manufacturing our product candidates, and establishing commercial supplies and sales, marketing, and distribution capabilities;
- our efforts to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and medical personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the costs associated with operating as a public company;
- the economic and other terms, timing of and success of our current and any future collaboration, licensing or other arrangements which we may enter in the future; and
- the timing, receipt, and amount of sales from our potential products, if approved.

If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, and our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our ADS holders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as limitations on our ability to incur additional debt, make capital

expenditures or declare dividends. If we raise funds through collaborations or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Risks Related to the Discovery, Development and Regulatory Approval of Product Candidates

Our approach to the discovery of product candidates based on our technology platform is unproven, and we do not know whether we will be able to develop any products of commercial value.

The success of our business depends primarily upon our ability to identify novel product candidates based on our structure-based drug discovery platform and to successfully develop and commercialize those product candidates. While we have had favorable preclinical study results for certain of our development programs, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approvals or in commercializing such product candidates. We also may be unsuccessful in identifying additional product candidates using our platform, and any of our product candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In particular, because all of our product candidates have been derived from our structure-based drug discovery platform, any failure of one of our development programs could create a perception that our other programs are less likely to succeed or that our discovery platform is not viable. Similarly, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our discovery platform and resulting product candidates.

If any of these events occur, our ability to successfully discover, develop and commercialize any product candidates may be impaired and the value of our company could decline significantly.

We are early in our development efforts and only have two product candidates, GSBR-1290 and ANPA-0073, in early clinical development. All of our other development programs are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts and have two product candidates, GSBR-1290 and ANPA-0073, in early clinical development. We completed a Phase 1 SAD study of GSBR-1290 in healthy volunteers in September 2022 for T2DM and obesity. Furthermore, we initiated the Phase 1b MAD study in January 2023 and completed dosing in healthy overweight subjects in March 2023. We also initiated the dosing of the Phase 2a study in May 2023 and expect to report topline data for the Phase 1b MAD study and Phase 2a study in the latter half of the fourth quarter of 2023. We also completed an ethnobridging study of GSBR-1290 in Japanese individuals and are planning to initiate an additional formulation bridging study to evaluate a tablet formulation of GSBR-1290 before the end of 2023, both in preparation for the planned global Phase 2b study in 2024. Additionally, we completed our Phase 1 SAD and MAD study for ANPA-0073 in healthy volunteers for IPF and PAH in September 2022. Our other product candidates are still in the preclinical or discovery stages. We will need to progress early product candidates through preclinical studies and submit INDs to the FDA or appropriate regulatory documents to applicable foreign authorities prior to initiating their clinical development.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies with favorable results;

- successful enrollment in, and completion of, clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- allowance to proceed with clinical trials under INDs by the FDA or under similar regulatory submissions by applicable foreign authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities;
- receipt of regulatory approvals from applicable regulatory authorities, including NDAs from the FDA and maintaining such approvals;
- making arrangements with third-party manufacturers, or establishing clinical and commercial manufacturing capabilities for our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- maintaining an acceptable safety profile of our products following approval; and
- building and maintaining an organization of people who can successfully develop our product candidates.

We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it will take several years before we can demonstrate the safety and efficacy of a product candidate sufficient to warrant approval for commercialization, if we can do so at all. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes. The results of prior clinical trials and preclinical studies are not necessarily predictive of future results, and may not be favorable, or receive regulatory approval on a timely basis, if at all.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of non-human primates (“NHP”) to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of NHPs available for drug development. This has caused the cost of obtaining NHPs for our preclinical studies to increase dramatically and, if the shortage continues, could also result in delays to our development timelines. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. Furthermore, the results from clinical trials or preclinical studies of a product candidate may not predict

the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted, or are conducting certain preclinical studies of our product candidates, the predictive value of these studies with respect to future testing in humans is limited, particularly in indications where animal models are less developed.

Even if our clinical trials are completed, the results may not be sufficient to obtain marketing approval for our product candidates. In clinical trials that are based on preclinical studies and early clinical trials, it is not uncommon to observe unexpected results, and many product candidates fail in clinical development despite very promising early results. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. In addition, in some cases, external experts or regulatory authorities disagreed with such companies' views and interpretations of the data and results from earlier preclinical studies or clinical trials. As we investigate GSBR-1290 for T2DM and obesity and ANPA-0073 for IPF and PAH, we may encounter new and unforeseen difficulties. For example, we recently completed a 13-week toxicology study evaluating GSBR-1290 in NHPs to support the protocol amendment for our planned Phase 2a study, in which we observed low to moderate levels of liver necrosis across all dosing groups, including the control group. Although the liver necroses observed in the NHP study were not attributed to GSBR-1290, the FDA may disagree or take action which could delay our GSBR-1290 program and harm our business and financial condition. Similarly any future product candidates we may develop may not be able to progress from preclinical to Phase 1 clinical development. For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any of the foregoing occurrences may harm our business, financial condition and prospects significantly.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

In order to obtain FDA approval to market our product candidates, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Clinical testing is expensive, time-consuming and subject to uncertainty. Conducting preclinical studies and clinical trials represents a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses.

Clinical trials may not be conducted as planned or completed on schedule, if at all. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with applicable regulatory authorities on trial design or implementation;
- delays in obtaining regulatory authorization to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations ("CROs"), other vendors, or clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different vendors and trial sites;
- delays in obtaining approval from one or more institutional review boards ("IRB") refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional participants, or withdrawing their approval of the trial;

- delays in recruiting suitable patients to participate in our ongoing and planned clinical trials;
- changes to the clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays in manufacturing sufficient quantities of our product candidates for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- participants choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial;
- occurrence of adverse events ("AEs") or serious adverse events ("SAEs") associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of SAEs in clinical trials of the same class of agents conducted by other companies;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- selection of clinical trial end points that require prolonged periods of clinical observation or analysis of the resulting data;
- clinical trials producing negative or inconclusive results;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or applicable foreign authorities to temporarily or permanently shut down due to violations of current good manufacturing practice ("cGMP") regulations or other applicable requirements, or contamination or cross-contaminations of product candidates in the manufacturing process;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol or other regulatory requirements or committing fraud; or
- changes in regulatory requirements, guidance, or feedback from regulatory agencies that require amending or submitting new clinical protocols or otherwise modifying the design of our clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or applicable foreign authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or applicable foreign authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, 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. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination and approval, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory requirements, as well as political, currency exchange and other economic risks relevant to such foreign countries. Investigators and patients may not be able to comply with clinical trial protocols if quarantines

impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff which in turn could adversely impact our clinical trial operations. Additionally, we may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with public health concerns. We have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. We experienced delays in our patient enrollment and our supply chain as a direct result of COVID-19 on our suppliers' ability to timely manufacture and ship certain supplies such as reagents and other lab consumables. These delays have previously impacted and could in the future adversely affect our business, financial condition, results of operations and growth prospects.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. For example, to facilitate potential commercial-scale manufacturing, we expect to transition from capsule formulations of our product candidates used for early clinical trials to tablet formulations, including the addition of excipients, in later stage clinical trials. While these formulation transitions are common for small molecule drug candidates, we cannot guarantee that we will not encounter delays or unexpected results in bridging studies or implementing necessary changes to the manufacturing process. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, which could adversely affect our business, operating results and prospects.

Patient enrollment is a significant factor impacting the duration of our clinical trials, along with treatment duration and completion of required follow-up periods. Clinical trials may be prolonged, or 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 as required by the FDA or applicable foreign authorities. For certain of our product candidates, including ANPA-0073, the conditions which we may evaluate include rare diseases with limited patient pools from which to draw. In some cases, patient populations for rare diseases are located at specific academic sites focused on such indications, often with multiple competing clinical trials. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. As noted above, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. In addition, the process of finding and diagnosing patients may prove costly.

The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If the actual number of patients with these diseases is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may

experience difficulties in patient enrollment or retention in our clinical trials for a variety of reasons. Patient enrollment and retention in clinical trials depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the design of the trial protocol;
- the existing body of safety and efficacy data for the product candidate;
- the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to adequately monitor patients during a trial, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied;
- the risk that patients will drop out of a trial before completing all site visits; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. For example, the impact of public health epidemics may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us or our partners from completing our clinical trials at all, and harm our ability to obtain approval for such product candidate. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or applicable foreign authorities, which would represent a significant setback for the applicable program. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. Such delays or failures could adversely affect our business, operating results and prospects.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates, any of which would limit the commercial potential of such product candidate.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials with a broader group of patients, or as use of

these product candidates becomes more widespread if they receive marketing approval, illnesses, injuries, discomforts and other AEs that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by participants. Many times, side effects are only detectable after investigational product candidates are tested in large-scale, Phase III trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current product candidates and any future product candidates has serious or life-threatening side effects or other side effects that outweigh the potential therapeutic benefit, the development of the product candidate may fail or be delayed, or, if the product candidate has received marketing approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition. In particular, because we are developing our product candidates for chronic indications, the FDA and applicable foreign authorities will likely require that our product candidates demonstrate a higher level of safety over a longer period of time than would be the case for product candidates intended for short-term use. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial value for the product candidate if approved. We may also be required to modify our trial plans based on findings in our ongoing clinical trials. In our completed Phase 1 SAD study of GSBR-1290, the following adverse events occurred and were considered probably or possibly related to the study drug: nausea, headache, vomiting, dehydration, decreased appetite, dizziness, and diarrhea. In our completed Phase 1 SAD and MAD study of ANPA-0073, the following adverse events occurred and were considered probably or possibly related to the study drug: blood creatine phosphokinase increase, dizziness, electrocardiogram T wave inversion, diarrhea, headache, lethargy, nausea, vomiting, chills, palpitations, and sinus tachycardia. However, further analysis may reveal AEs inconsistent with the safety results observed. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

In addition, if any of our product candidates receive marketing approval, the FDA could require us to include a black box warning in our label or adopt a REMS, to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. For example, the FDA has required that the product labels of approved drugs targeting GLP-1R include a black box warning related to the risk of thyroid C-cell tumors based on rodent carcinogenicity studies. While we have not yet conducted carcinogenicity studies for GSBR-1290, because it also targets GLP-1R, it is possible that absent compelling data to the contrary, the FDA and applicable foreign authorities will similarly require a black box warning for GSBR-1290 if it is approved for marketing. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several other potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients;

- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties;
- we may need to conduct a recall;
- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

As an organization, we have never conducted later-stage clinical trials or submitted an NDA, and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates, and we will need to successfully complete pivotal clinical trials in order to seek FDA or applicable foreign authority approval to market GSBR-1290, ANPA-0073 and any future product candidates we may develop. Carrying out clinical trials and the submission of NDAs is complicated. We completed a Phase 1 SAD study for GSBR-1290 in healthy volunteers in September 2022. Additionally, we completed our Phase 1 SAD and MAD study for ANPA-0073 in healthy volunteers for IPF and PAH. We have not conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an NDA or other applicable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we have had no interactions with the FDA or applicable foreign authorities and cannot be certain how many clinical trials of our product candidates will be required or how such trials will have to be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing our product candidates.

The marketing approval processes of the FDA and applicable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.

The time required to reach approval by the FDA and applicable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained marketing approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain marketing approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive FDA marketing approval of an NDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or applicable foreign authorities, that such product candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or

clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA and applicable foreign authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or could object to elements of our clinical development program.

The FDA or applicable foreign authorities can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for various reasons, including the following:

- the FDA or applicable foreign authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or applicable foreign authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or applicable foreign authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or applicable foreign authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA's or the applicable foreign authority's requirement for additional nonclinical studies or clinical trials;
- the FDA or the applicable foreign authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA or applicable foreign authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or applicable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign marketing approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain marketing approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

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

Because we have limited financial and managerial resources, we focus on specific product candidates, indications and discovery programs. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation

decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. 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 future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, in recent years, a number of companies have entered the drug discovery industry utilizing different AI approaches. The success of other such AI approaches to drug discovery could create more competition for us. We believe that we must continue to invest a significant amount of time and resources in our platform technologies to maintain and improve our competitive position.

We may not be able to obtain or maintain orphan drug designations or exclusivity for our product candidates, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States alone. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the targeted indication, then the drug is entitled to a seven-year period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same chemical entity for the same indication for the exclusivity period except in limited situations, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation.

We intend to pursue orphan drug designation for one or more of our product candidates, as well as for potential other future product candidates. Obtaining orphan drug designations is important to our business strategy; however, obtaining an orphan drug designation can be difficult and we may not be successful in doing so. Even if we were to obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

We have conducted, or plan to conduct, our initial clinical studies for GSBR-1290, ANPA-0073, LTSE-2578 and our other product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We have conducted our initial clinical studies for GSBR-1290 and ANPA-0073 in Australia, and will likely conduct our Phase 1 studies for other drug candidates in Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or applicable foreign authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practices ("GCP") regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any applicable foreign authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We believe that clinical data generated in Australia will be accepted by the FDA and its foreign equivalents outside of Australia; however, there can be no assurance the FDA or applicable foreign authorities will accept data from any other clinical studies that we may conduct in Australia. If the FDA or applicable foreign authorities do not accept any such data, we would likely be required to conduct additional Phase 1 clinical studies, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

Conducting clinical trials outside the United States exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

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

From time to time, we may publicly disclose interim, preliminary or topline data from our clinical trials, which are 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 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 and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously made public. As a result, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between topline, preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, 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 value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the 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 approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, it does not mean that comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may negatively impact the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign marketing approvals and establishing and maintaining 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 or any future collaborator fail to comply with the regulatory requirements in international markets or fail to 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, which would adversely affect our business, prospects, financial condition, and results of operations.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and applicable foreign authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, furloughed critical employees and ceased critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and applicable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or applicable foreign authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or applicable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We rely on third parties for the manufacture of our product candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Our active pharmaceutical ingredients and drug product for our product candidates are currently provided by a single-source supplier, WuXi STA, and we expect to rely on this supplier for the foreseeable future. While we believe that adequate alternative sources for such supplies exist, there is a risk that, if supplies are interrupted, it would materially harm our business.

Furthermore, we do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or an applicable foreign authority does not approve these facilities for the manufacture of our product candidates

or if the FDA or applicable foreign authority, withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

In the event that any of our manufacturers fails to comply with applicable requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of future global pandemics, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on our third-party manufacturers or require us to obtain a license from such manufacturers in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any product produced by the new manufacturer is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third-party's failure to execute on our manufacturing requirements on commercially reasonable terms and timelines, if at all, and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our drug specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP or similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- reliance on single source manufacturers for drug substances and drug products;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;

- misappropriation of proprietary information, including our trade secrets and know-how;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

In addition, we do not have any long-term commitments or supply agreements with our third-party manufacturers. We may be unable to establish any supply agreements with our third-party manufacturers or do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of our product candidates or such quantities at an acceptable cost, which may harm our business and results of operations.

We intend to rely on third parties to conduct, supervise and monitor our discovery research, preclinical studies and clinical trials. If those third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not currently have the ability to independently conduct certain discovery research, preclinical studies and clinical trials for our product candidates. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies or clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the good laboratory practices ("GLPs"), and GCPs, which are regulations and guidelines enforced by the FDA and applicable foreign authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we will rely on CROs to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or applicable foreign authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of participants, we may be required to repeat clinical trials, which would delay the marketing approval process.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may

not be able to obtain marketing approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

In addition, quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, which could disrupt our clinical timelines, which could have a material adverse impact on our business, prospects, financial condition, and results of operations. If our relationship with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, we may encounter challenges or delays in the future and we cannot assure you that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or applicable foreign authorities. The FDA or applicable foreign authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or applicable foreign authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or applicable foreign authorities and may ultimately lead to the denial of marketing approval of our current and future product candidates.

We have entered into, and may in the future enter into, collaboration agreements and strategic alliances to maximize the potential of our structure-based drug discovery platform and product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

Part of our business strategy is to explore additional collaborations with third parties to further strengthen our platform capabilities and to leverage our platform for external opportunities where partners bring additional disease biology understanding, development and commercial expertise, regional insights or other complementary capabilities. We may therefore form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our structure-based drug discovery platform or our product candidates and any future product candidates that we may develop, including in territories outside the United States or for certain indications. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other anticipated benefits that led us to enter into the arrangement.

Research and development collaborations are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and may not commit sufficient efforts and resources, or may misapply those efforts and resources;
- collaborators may not pursue development and commercialization of our structure-based drug discovery platform or collaboration product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results or changes in their strategic focus;
- collaborators may delay, provide insufficient resources to, or modify or stop clinical trials for our structure-based drug discovery platform or collaboration product candidates;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our products or product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital and personnel to pursue further development or commercialization of our structure-based drug discovery platform or the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our structure-based drug discovery platform or product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. In addition, there have been a significant number of recent business combinations among large pharmaceutical and biomedical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. In addition, we may face regulatory obstacles in completing such transactions. If we are unable to do so, we

may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our structure-based drug discovery platform or product candidates or bring them to market and generate revenue.

Additionally, we may sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. If collaborations occur, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

Our products require specific constituents to work effectively and efficiently, and rights to those constituents are, and in the future may be, held by others. We may also seek to in-license third-party technologies to enhance our structure-based drug discovery platform. We may be unable to in-license any rights from constituents, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which could harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology in order to establish or maintain our competitive position in the market. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates or our structure-based drug discovery platform could delay the development and commercialization of our product candidates in certain geographies or limit our ability to discover and develop new product candidates, which could harm our business prospects, financial condition, and results of operations.

Our existing discovery collaboration with Schrödinger is important to our business. If we are unable to maintain this collaboration, or if this collaboration is not successful, our business could be adversely affected.

In October 2020, Lhotse, our wholly-owned subsidiary, entered into the Lhotse-Schrödinger Agreement. Under the Lhotse-Schrödinger Agreement, Schrödinger uses its technology platform to perform virtual screens of members of the target class of human integrins, and we and Schrödinger collaborate to facilitate prioritization of targets, perform target validation and analysis, identify leads and perform lead optimization. Schrödinger has granted us an exclusive license to certain intellectual property related to our product candidates discovered under this agreement. See the Part II. Item 2. "Management's Discussion and Analysis of Results of Operations and Financial Condition—Lhotse Collaboration Agreement with Schrödinger, LLC" of this Quarterly Report.

Because we currently rely on Schrödinger for a substantial portion of our discovery capabilities, if Schrödinger delays or fails to perform its obligations under the Lhotse-Schrödinger Agreement, disagrees with our interpretation of the terms of the collaboration or our discovery plan or terminates the Lhotse-Schrödinger Agreement, our pipeline of product candidates would be adversely affected. Schrödinger may also fail to properly maintain or defend the intellectual property we have licensed from them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive. Additionally, either party has

the right to terminate the collaboration pursuant to the terms of the Lhotse-Schrödinger Agreement. If our collaboration with Schrödinger is terminated, especially during our discovery phase, the development of our product candidates would be materially delayed or harmed.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Reliance on third parties to manufacture or commercialize our current or any future product candidates, and on collaborations with additional third parties for the development of our current or any future product candidates, requires us to share trade secrets with these third parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets could harm our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information, including to competitors. In addition,

competitors or other third-parties may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

The adoption and deployment of artificial intelligence ("AI") in our, and any third-party collaborators' operations, and in particular our and any third-party collaborators' research and development ("R&D") efforts to explore new targets and develop effective products, may not be effective and may expose us to risk.

The industry in which we compete is characterized by rapid technological advancements, frequent introductions of new products and heavy competition. The discovery of new products and targets remain vital to our success and the implementation by us and by any third-party collaborators of artificial intelligence technologies and processes, including advanced predictive analytics, computational approaches for drug discovery and so-called "generative" AI, has the potential to provide significant benefits in these areas. Use of AI in our efforts may be difficult to deploy successfully due to operational issues inherent in such methods. In particular, the AI algorithms utilize machine learning and predictive analytics which may lead to flawed, biased, and inaccurate results, which could lead to ineffective product or target candidates and exposure to competitive and reputational harm. We face increased competition from other companies that are using AI and related methods for drug discovery, some of which have more resources than we do and may have developed more effective methods than we and any third-party collaborators have, which may reduce our and any third-party collaborator's effectiveness in identifying potential targets and attracting additional collaborators to work with us. Even with the successful implementation of AI, we may fail to correctly identify indications and allocate resources efficiently, which could adversely impact our pipeline and ability to compete effectively.

Further, AI presents additional risks and challenges, especially as the use of these technologies becomes more important to our operations over time. Generative AI may be used improperly or inappropriately which could lead to the tainting of our proprietary information and render us unable to qualify for patent protection. Their use by people, including our vendors, employees, suppliers and contractors, with access to our proprietary and confidential information, including trade secrets, may continue to increase and may lead to the release of such information, which may impact our ability to realize the benefit of our intellectual property. Our use of generative AI platforms may lead to novel and urgent cybersecurity risks, which may adversely affect our operations and reputation, as well as the operations of any third-party collaborators. Emerging ethical issues surround the use of AI, and we may be subject to reputational and legal risk if our deployment or use of AI becomes controversial. Regulators could limit our, or any third-party collaborator's ability to develop or implement AI-based technologies as part of measures taken against us or any third-party collaborators in particular or as a consequence of broader legislation, which could have an adverse effect on our or any third-party collaborators' business, results of operations and financial conditions. Uncertainty in the legal regulatory regime may require significant resources to modify and maintain business practices to comply with U.S. and non-U.S. laws, the nature of which cannot be determined at this time.

Risks Related to Commercialization of Our Product Candidates

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if we obtain any marketing approval for our current or any future product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs, for any clinical trials that we may conduct post-approval. Any marketing approvals that we receive for our current or future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we or a regulatory authority discover previously unknown problems with a drug, such as AEs of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our current or future product candidates, a regulatory authority may, among other things:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or NDA supplement, or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict or suspend the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we

may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could cause changes to or delays in the drug review process, or suspend or restrict marketing approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

Even if our current or future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our current or future product candidates receive marketing approval, they may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our current or future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the clinical indications for which the product candidate is approved;
- the efficacy and potential advantages compared to alternative treatments and therapies;
- the timing of market introduction of the product as well as competitive products;
- effectiveness of sales and marketing efforts;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such product for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the availability of third-party coverage and adequate reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- the strength of marketing and distribution support;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates, if approved, to find market acceptance would harm our business and could require us to seek additional financing.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Commercial payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a third-party payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our structure-based drug discovery platform. If we fail to stay at the forefront of technological change in utilizing our platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and platform.

In addition, we face competition with respect to our current product candidates and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are aware of GLP-1R small molecules in development by Pfizer, Eli Lilly, and Qilu Regor Therapeutics Inc. There are currently approved GLP-1R peptides for the treatment of diabetes and obesity marketed by Novo Nordisk, Eli Lilly, AstraZeneca, and Sanofi. We are also aware of other GLP-1R plus dual/tri incretin targeting peptides in development by Eli Lilly, Jiangsu Hansoh Pharmaceutical Group Co., Ltd., Boehringer Ingelheim, Altimmune, Inc., Carmot Therapeutics, Inc., and Sciwind Biosciences Co., Ltd. Additionally, we are aware of APJR targeted product candidates in development for COVID-19 acute respiratory distress syndrome by CohBar, Inc.; IPF, systemic sclerosis interstitial lung disease, and kidney nephrotic syndrome by Apie Therapeutics; and muscle atrophy by BioAge Labs, Inc. Both Amgen and BMS have APJR targeted product candidates for heart failure. Furthermore, we are aware of LPA1R targeted product candidates in development for IPF by BMS, Horizon Therapeutics plc, and DJS Antibodies Ltd; myelin restoration and neuroinflammation by Pipeline Therapeutics.

Many of our competitors, either alone or with their collaborators, have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the timing and scope of marketing approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Any failure to compete effectively could harm our business, financial condition and operating results.

In addition, we and any third-party collaborators are facing increasing competition from companies utilizing AI and other computational approaches for drug discovery. Some of these competitors are involved in drug discovery themselves and/or with partners, and others develop software or as well as other tools utilizing AI which can be used, directly or indirectly, in drug discovery. To the extent these other AI approaches to drug discovery prove to be successful, or more successful, than our and any third-party collaborators' approach, our business, financial condition and operating results could be adversely affected.

If the market opportunities for any of our product candidates are smaller than we estimate, even assuming approval of a product candidate, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we as a company commercialized a product. If any of our product candidates ultimately receives marketing approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy

and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing, degree of success and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and

- the timing and success or failure of preclinical studies or clinical trials for our product candidates or any competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our ADSs could decline substantially. Such a price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are highly dependent on the services of our senior management team and if we are not able to retain these members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we will need to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on terms acceptable to us, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates and our business will be limited and we may experience constraints on our development objectives.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future marketing approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of June 30, 2023, we had 77 full-time employees. As we advance our research and development programs, we may need to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, discovery biology, chemistry, manufacturing, general and administrative matters related to being a public company, regulatory affairs and, if any of our product

candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities, to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We conduct certain research and development operations through our Australian wholly-owned subsidiaries. If we lose our ability to operate in Australia, or if any of our subsidiaries are unable to receive the research and development tax credit allowed by Australian regulations or are required to refund any research and development tax credit previously received or reserve for such credit in our financial statements, our business and results of operations could suffer.

In 2021, we formed two wholly-owned Australian subsidiaries, Annapurna Bio Pty Limited (“Annapurna AU”) and Gasherbrum Bio Pty Limited (“Gasherbrum AU”), to conduct various preclinical and clinical activities for our product and development candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our lead products in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidates in Australia will be accepted by the FDA or applicable foreign authorities.

In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. Although we have previously claimed a refundable research and development tax credit there is a possibility that we may not be able to claim such credit or we might qualify for a lesser credit. If we lose our ability to operate Annapurna AU or Gasherbrum AU in Australia, or if in the future we are ineligible or unable to receive the research and development tax credit or are required to refund any research and development tax credit previously received or have to reserve for such credit in our financial statements, or if the Australian government significantly reduces or eliminates the tax credit, our business and results of operation may be adversely affected.

Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, other healthcare laws and regulations and health data privacy and security laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims

laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, as well as our proposed sales and marketing programs. In addition, we may be subject to health information privacy and security laws by the federal government, the states and other jurisdictions in which we may conduct our business. The laws that may affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws, such as the Civil Monetary Penalties Law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private). Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and covered contractors, individuals or entities that perform certain services on behalf of a covered entity that involves the use or disclosure of individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- The Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the CMS information related to: (i) payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and/or information regarding drug pricing, state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal

government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers, state laws and regulations that require drug manufacturers to file reports relating to drug pricing and marketing information, and state and local laws that require the registration of pharmaceutical sales representatives; and

- state and foreign laws that govern the privacy and security of personal information, including health-related information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the limited statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including certain scientific advisory board agreements with physicians who are compensated in the form of ordinary shares or share options in addition to cash consideration, could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA,") was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states on procedural grounds without specifically ruling on the constitutionality of the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-

of-pocket cost and through a newly established manufacturer discount program. It is possible the ACA will be subject to judicial or Congressional challenges in the future.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries, presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, in July 2021, the Biden administration released an executive order with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs the HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

We cannot predict what healthcare reform initiatives may be adopted in the future. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

If we or our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state, and local laws and regulations in the United States and foreign jurisdictions governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws and regulations

is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, and results of operations.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- a diversion of management's time and our resources;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- the inability to commercialize any product candidate that we may develop;
- injury to our reputation and significant negative media attention; and
- a decline in our ADS price.

We currently hold approximately $10.0 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised or experienced significant disruptions of our information technology systems or data security incidents, we could experience adverse consequences including but not limited to significant financial, legal, regulatory, business and reputational harm; litigation; fines and penalties; disruptions of our business operations; loss of revenue or profits; loss of customers or sales; or other adverse consequences.

We are increasingly dependent on information technology systems and infrastructure, including mobile and third-party, cloud-based technologies, to operate our business. In the ordinary course of our business, we may collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we

do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our sensitive information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on or transmitted between those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external exploits of our technology environment, including by organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. Further, due to the COVID-19 pandemic, we enabled all of our employees to work remotely, which may make us more vulnerable to cyberattacks. Cyberattacks are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, supply chain attacks, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Data security incidents and other inappropriate access can also be difficult to detect, can result from the intentional or inadvertent actions or inactions of those with authorized access to our network and any delay in identifying them may lead to increased harm. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of, or cyber incidents directed at, our or our third-party vendors’ and/or business partners’ information technology systems could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in a variety of adverse effects, including financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we or our third-party collaborators, consultants, contractors, suppliers, vendors or service providers were to suffer an actual or likely attack or breach, for example, that involves the unauthorized access to or use or disclosure of personal or health information for which we are responsible may require us, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions (including mandatory corrective action or requirements to verify the correctness of database contents), and consuming, distracting and expensive litigation, any of which could result in increased costs to us, and result in significant legal and financial exposure, or other harm to our business and reputation.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we have no reason to believe that we have been subject to any significant system failure, accident or security breach to date, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we have implemented security measures intended to protect our information technology systems and infrastructure, such measures may not successfully prevent service interruptions or security incidents.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and applicable foreign authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or applicable foreign authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a negative impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, industry standards, contractual obligations, policies and other obligations related to data security and privacy. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions, which could include civil, criminal or administrative penalties, private litigation, reputational harm, and/or adverse publicity and could negatively affect our operating results and business, financial condition, results of operations and prospects.

The global data protection landscape is rapidly evolving, and we are or may become subject to or be affected by evolving federal, state and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal and state health information privacy laws, state data breach notification laws, and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health information and other personal information and could apply to our operations. These laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal information. HIPAA, as amended by HITECH, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations governing the privacy, processing and protection of personal information. For example, the California Consumer Privacy Act of 2018 ("CCPA") requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the California Privacy Rights Act of 2020 ("CPRA") expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Several other states, including Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws, and similar laws have been passed or are being considered in other states, as well as at the federal and local levels. While these state laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that is expected to increase data breach litigation. The Attorney General and local government attorneys may also bring enforcement actions for alleged violations of the CCPA. Although there are some exemptions for clinical trial data and health information, the CCPA may impact our business activities and increase our compliance costs and potential liability. Further, the CPRA recently took effect in California. The CPRA significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. While other state privacy laws are similar to the CCPA and CPRA, certain aspects of these other state privacy statutes remain unclear, resulting in further legal uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to comply. The enactment of additional laws could have potentially

conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by these laws or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU GDPR, the United Kingdom's GDPR ("UK GDPR"), and the Personal Information Protection Act in South Korea, impose strict requirements for processing personal data. Under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the European Economic Area ("EEA") and United Kingdom ("UK") to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. Recently, however, the UK has implemented an International Data Transfer Agreement/Addendum and the EU-U.S. Data Privacy Framework has been introduced, (the latter of which allows for transfers of personal data for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), but these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

The EU has also proposed a Regulation on Privacy and Electronic Communications ("ePrivacy Regulation") which, if adopted, would impose new obligations on the use of personal data in the context of electronic communications, particularly with respect to online tracking technologies and direct marketing. Additionally, the EU adopted the EU Clinical Trials Regulation, which came into effect on January 31, 2022. This regulation imposes new obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access information about clinical trials.

The Cayman Islands Data Protection Act imposes obligations on data controllers in relation to the processing of personal data, and also introduced rights for data subjects (which may be subject to various exemptions), including, among others: (a) personal data must be processed fairly and on the basis of one of the grounds for processing as set out in the Data Protection Act; (b) personal data must be obtained for a specified lawful purpose; (c) personal data must be adequate, relevant and not excessive in relation to the purpose for which it was processed; (d) personal data must be accurate and, where necessary, kept up to date; (e) personal data must not be kept for longer than is necessary; (f) personal data must be processed in accordance with the rights of the data subject; (g) appropriate technical and organizational security measures must be taken to

prevent unauthorized or unlawful processing, accidental loss or destruction of personal data; and (h) the personal data may not be transferred to a country unless that country ensures an adequate level of protection for the rights and freedoms of data subjects.

In recent years, authorities of the PRC have promulgated certain laws and regulations in respect of information security, data collection and privacy protection regulations in the PRC, including the Cybersecurity Law of the PRC, the Provisions on Protection of Personal Information of Telecommunication and Internet Users, the Data Security Law of the PRC which became effective from September 1, 2021, and the Personal Information Protection Law of the PRC which became effective from November 1, 2021. Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual prior consent shall be obtained, unless other circumstances clearly mentioned therein to the contrary. Further, any data processing activities in relation to the sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old are not allowed unless such activities have a specific purpose, are highly necessary and have taken strictly protective measures.

In addition to data privacy and security laws, we contractually may be subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. In particular, compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, increase our costs of legal compliance, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' suppliers' ability to operate in certain jurisdictions. Our or our service providers' and vendors' actual or perceived failure to comply with U.S. and foreign data protection laws and regulations could result in threatened or actual government investigations and/or enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we or our third party service providers have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

We publish privacy policies, self-certifications, and other documentation regarding our collection, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies, certifications, and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies, certifications, and documentation. Such failures can subject us to potential international, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices.

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 Mainland China, Hong Kong, Australia, the Cayman Islands 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.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, 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.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. For instance, the recently enacted Inflation Reduction Act ("IRA") imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. The Tax Cuts and Jobs Act of 2017 ("TCJA"), as amended by the Coronavirus Aid, Relief, and Economic Security Act significantly reformed the United States Internal Revenue Code of 1986, as amended (the "Code"), by lowering U.S. federal corporate income tax rates, changing the utilization of future net operating loss ("NOL") carryforwards, permitting for the expensing of certain capital expenditures, eliminating the option to currently deduct research and development expenditures and requiring taxpayers to capitalize and amortize U.S.-based and non-U.S.-based research and development expenditures over five and fifteen years, respectively. and putting into effect significant changes to U.S. taxation of international business activities. The IRA, TCJA, or any future tax reform legislation could have a material impact on the value of our deferred tax assets, result in significant one-time charges, and increase our future tax expenses.

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 affect our business, financial condition, results of operations and the market price of our ADSs.

Due to our operations in China, our business, results of operations, financial condition and prospects may be influenced to a certain 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 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 a decrease in economic activity in China, which may 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 seeking to register securities with the SEC. Although we do not have a VIE structure, due to our 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 operations in China could 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 and geopolitical tensions between China and the United States increase, the Chinese government may intervene with our operations and our business in China and United States, as well as the market price of our ADSs, may also be affected.

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

The Chinese government has some 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 that could potentially affect our business, financial condition and results of operations. Furthermore, recent statements made by the Chinese government, including the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law published on July 6, 2021, and a new set of regulations consisting of the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (the "Trial Measures") and five supporting guidelines published on February 17, have indicated an intent to increase the government's oversight and control over offerings of companies with certain amount of operations in China that are to be conducted in foreign markets, as well as foreign investment in certain qualified issuers. If we were to become subject to the direct intervention or influence of the Chinese government at any time due to changes in laws or other unforeseeable reasons, it may require a material change in our operations and/or the value of our ADSs.

Changes in U.S. and Chinese regulations may 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 certain operations based in China. 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 research 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 certain operations based in China, 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 certain operations based in China, 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 certain operations based in China. 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 by China. However, it is possible that our periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and 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 China Securities Regulatory Commission ("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 new Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, regulations and guidelines relating to the multi-level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business.

China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. China's new 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.

Additionally, China's Cyber Security Law, promulgated by the Standing Committee of the National People's Congress in November 2016 and came into effect in June 2017, and the Administrative Measures for the Hierarchical Protection of Information Security promulgated by the Ministry of Public Security, National Administration of State Secrets Protection, State Cryptography Administration and other government authority in June 2007, 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 of the entity's information and network systems. These levels range 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 ("CAC") has taken action against several Chinese internet companies in connection with their initial public offerings 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 Cybersecurity Review Measures, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests."

On July 10, 2021, the CAC published a draft revision to the existing Cybersecurity Review Measures for public comment (the "Revised Draft CAC Measures"). On January 4, 2022, together with 12 other Chinese regulatory authorities, the CAC released the final version of the Revised Draft CAC Measures (the "Revised CAC Measures"), which came into effect on February 15, 2022. Pursuant to the Revised CAC Measures, critical information infrastructure operators procuring network products and services, and online platform operators (as opposed to "data processors" in the Revised Draft CAC Measures) carrying out data processing activities which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the "Draft Management Regulations"), under which data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Draft Management Regulations reiterate that data processors shall be subject to cybersecurity review if (i) they process personal information of more than one million persons and they are aiming to list on foreign stock markets, or (ii) their data processing activities affect or may affect Chinese national security. The Draft Management Regulations also request data processors seeking to list on foreign stock markets to annually assess their data security by themselves or through data security service organizations, and submit the assessment reports to relevant competent authorities. As the Draft Management Regulations are released only for public comment, the final version and the effective date thereof is subject to change.

As of the date of this Quarterly Report, we have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator," "online platform operator" or "data processor," or requiring us to go through the cybersecurity review procedures pursuant to the Revised CAC Measures and the Draft Management Regulations. Based on our understanding of the Revised CAC Measures, and the Draft Management Regulations if enacted as currently proposed, we do not expect to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over PRC national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information for more than one million users or

persons. However, there remains uncertainty as to how the Revised CAC Measures, and the Draft Management Regulations if enacted as currently proposed, will be interpreted or implemented; for example, neither the Revised CAC Measures nor the Draft Management Regulations provides further clarification or interpretation on the criteria for determining those activities that “affect or may affect national security” and relevant Chinese regulatory authorities may interpret it broadly. Furthermore, there remains uncertainty as to whether the Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Revised CAC Measures and the Draft Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised CAC Measures, the Draft Management Regulations or other laws and regulations related to privacy, data protection and information security.

Also, 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 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.

In addition, certain industry-specific laws and regulations affect the collection and transfer of data in the PRC. The Regulations on the Administration of Human Genetic Resources of the PRC (the “HGR Regulation”) was promulgated by the State Council in May 2019 and came into effect in July 2019. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China’s human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China’s human genetic resources after satisfaction of all requirements under the HGR Regulation and other applicable laws, such as (i) China’s human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China’s human genetic resources information being provided after required filing and information backup procedures have been gone through. In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China’s human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. In May 2023, the Ministry of Science and Technology published the Implementing Rules for the Regulations on the Administration of Human Genetic Resources (the “HGR Implementing Rules”) which came into effect in July 2023. The HGR Implementing Rules have, among other things, further clarified the scope of China’s human genetic resources information, improved the procedure rules for applicable approval, filing and security review, and refined the provisions with respect to the forbiddance on the collection, preservation and export of China’s human genetic resources by foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals. There remain significant uncertainties as to how various provisions of the HGR Regulation and the related laws and regulations may be interpreted and implemented. Given such uncertainty, although we

have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC, the HGR Implementing Rules and other applicable laws in our utilizing of and dealing with China's human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation, the Biosecurity Law of the PRC and the HGR Implementing Rules.

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 China's new Cyber Security Law and 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 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, the Revised CAC Measures and the recent Chinese government actions could adversely affect our ability, on favorable terms, to raise capital, including engaging in follow-on offerings of our securities in the U.S. market.

The approval of, filing or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.

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.

On July 6, 2021, the relevant Chinese government authorities published the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law. These opinions call for strengthened regulation over illegal securities activities and increased supervision of overseas listings by China-based companies, and propose to take effective measures, such as promoting the construction of relevant regulatory systems to regulate the risks and incidents faced by China-based overseas-listed companies.

Furthermore, on February 17, 2023, the CSRC promulgated a new set of regulations that consists of the Trial Measures and five supporting guidelines which came into effect on March 31, 2023 to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form. According to the Trial Measures, we may be required to submit filings to the CSRC in connection with future issuances of our equity securities to foreign investors. For more details, see the Part I. Item 1. "Business—Regulation—Other Significant Chinese Regulation Affecting Our Business Activities in China" of our Annual Report on Form 10-K for the year ended December 31, 2022.

As of the date of this Quarterly Report, we have not received any inquiry, notice, warning or sanction regarding obtaining approval, completing filings or other procedures in connection with our previous issuances of securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. Based on the above and our understanding of the newly issued Trial Measures and the supporting guidelines, after they came into effect on March 31, 2023, we will not at once be required to submit an application to the CSRC for our previous issuances of securities to foreign investors, but if we intend to make any subsequent securities offering in the same overseas market, we may be required to submit filing with the CSRC within three working days after such subsequent securities offering is completed. However, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities, and we cannot assure you that the relevant Chinese regulatory authorities, including the CSRC, would reach the same conclusion as us. If it is determined in the future that the approval of, filing or other procedure is required with the CSRC or any other regulatory authority is required for our previous issuances of securities to foreign investors, or if we are required to complete relevant procedures for our future issuances of securities to foreign investors, it is uncertain whether we will be able and how long it will take for us to obtain the approval or complete the filing or other procedure or obtain a waiver for such procedures, despite our best efforts. If we, for any reason, are unable to obtain or complete, or experience significant delays in obtaining or completing, the requisite relevant approval(s), filing(s) or other procedure(s), the regulatory authorities may impose fines and penalties on our operations in China, limit our operating privileges in China, revoke our business licenses, delay or restrict the repatriation of the proceeds from securities offerings into China or take other actions that could have an adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of the ADSs. Any uncertainties and/or negative publicity regarding the aforementioned approval(s), filing or other procedure(s), the interpretation and implementation of existing laws and regulations, or any further laws, regulations or interpretations that may be released and enacted in the future could have a material adverse effect on the trading price of the ADSs.

Pharmaceutical companies operating 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 current and planned operations in China.

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, labeling, 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. In particular, we are subject to many of these laws and regulations because our wholly-owned subsidiary, Basecamp Bio, through which we conduct our technology development and early discovery activities, operates primarily in China. Violation of applicable laws and regulations may materially and adversely affect our business. 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.

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

As a company with operations in China, our business is subject to risks associated with conducting business outside the United States. In addition to our technology development and early discovery activities through Basecamp Bio in China, 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 RMB;
- increasing geopolitical tensions between the U.S. and China and 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;
- 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 technology development and early discovery 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 wastewater, 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 third-party manufacturers and other service providers 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.

There are legal and operational risks associated with having our early discovery and preclinical operations 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 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 40 years, growth has been uneven across different regions and among various economic sectors of China. 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.

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

Chinese laws and regulations govern our operations in China and the implementation of these 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. The Chinese legal system is evolving rapidly and the Chinese laws, regulations, and rules may change quickly with little or no advance notice. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the non-precedential nature of

these decisions, the interpretation of these laws, rules and regulations may contain inconsistencies, the enforcement of which involves uncertainties. These uncertainties could materially and adversely affect our business and results of operations.

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 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. 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.

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 ("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 you 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 the IPO and to capitalize or otherwise fund our Chinese operations, including our technology development and early discovery activities through Basecamp Bio, may be negatively affected, which could materially and adversely affect 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 SAFE Circular 37, which 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 you could be materially and adversely affected.

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 ("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 our 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 ordinary 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 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 immediately 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 buying and 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 a future securities 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. Even if we believe no SAT Circular 7 reporting is required on the basis that such an 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 such an offering 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 stock incentive plans are subject to such regulation. We plan to assist our employees to register their equity awards. However, any failure of our Chinese individual beneficial owners and holders of equity awards 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 Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our markets. Our success depends in large part on our ability to obtain and maintain patent protection for our product candidates and their intended uses, maintain trade secret protection of our platform technologies, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued, or may not result in issued patents that will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies or products.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including due to delays as a result of global pandemics impacting our or our licensors' operations. Further, we may decide to not pursue or seek patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights. Or we may not be able to obtain a patent on such technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our product candidates, or to block competitor products or product candidates that are similar to ours.

Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. The claims in our pending patent applications directed to composition of matter of our product candidates may not be considered patentable by the United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or that the claims in any of our issued patents will be

considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions for which many legal principles continue to change. In recent years, patent rights have been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and we or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other foreign jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

The claims in our pending patent applications directed to our product candidates and/or technologies may not be considered patentable by the USPTO or by patent offices in foreign countries. Any such patent applications may not be issued as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. There may be double patenting among our own patents, which the patent examiner(s) fail to raise during prosecution. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates.

Our pending patent applications may be challenged in the USPTO or in patent offices in foreign countries. Also, because the issuance of a patent is not conclusive as to its scope, validity or enforceability, even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or patent offices in foreign countries or our issued patents may be subject to post-grant review (“PGR”) proceedings, oppositions, derivations, reexaminations, or *inter partes* review (“IPR”) proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in our patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, only limited protection may be available and our patent portfolio may not provide us with sufficient rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates and technologies, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. We expect to rely on CROs and third parties to generate chemical molecules and important research data. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors or CROs that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to

share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to complete development of, or commercialize, our products. Although we require all of our employees, consultants, collaborators, CROs, contract manufacturers, advisors and any third parties who have access to our proprietary know-how, information or technologies to enter into confidentiality agreements, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information may not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

We may rely on one or more in-licenses from third parties. If we lose these rights, our business may be materially adversely affected, and if disputes arise with one or more licensors, we may be subjected to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technologies covered by these license agreements.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would adversely affect our business. We may need to cease use of the technology covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, and may allow our competitors access to the same technologies licensed to us. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive for commercializing our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights

to the intellectual property surrounding the additional product candidates and technology that we may seek to acquire.

We may in the future enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business. Our rights to use the technology we license are subject to the continuation of and compliance with the terms of those agreements. These intellectual property license agreements may require of us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy-related proceedings, the terms of the license agreements may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us, which could limit our ability to implement our current business plan and materially adversely affect our business, financial condition, results of operations and prospects.

We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

In some cases, we may not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of those patents against third parties. Hence, our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed in a manner consistent with the best interests of our business. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control, and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Moreover, disputes may arise with respect to our licensing or other upstream agreements, including:

- the scope of rights granted under the agreements and other interpretation-related issues;
- whether and the extent to which our systems and consumables, technologies and processes infringe on 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 agreements 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 spite of our efforts to comply with our obligations under our in-license agreements, our licensors might conclude that we have materially breached our obligations under our license agreements and might therefore, including in connection with any aforementioned disputes, terminate the relevant license agreement, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If any such in-license is terminated, or if the licensed patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to market or develop products similar to ours. In addition, absent the rights granted to us under such license agreements, we may infringe the intellectual property rights that are the subject of those agreements, we may be subject to litigation by the licensor, and if such litigation by the licensor is successful we may be required to pay damages to such licensor, or we may be required to cease our development and commercialization activities which are deemed infringing, and in such event we may ultimately need to modify our activities or products to design around such infringement, which may be time- and resource-consuming, and which may not be ultimately successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Our intellectual property licensed from third parties may be subject to retained rights.

Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"); these include the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel, patent annuity service providers, or our licensing partners to pay these fees due to non-U.S. patent agencies. If these fees are not paid to the USPTO or the non-U.S. patent agencies when due, our rights to such patents or patent applications may be abandoned or otherwise materially impaired.

The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, and other similar provisions during the patent application process. For example, many countries, including the U.S. and China, require a foreign filing license to seek patent protection in a country outside of the inventor's or invention's country. Each country's laws regarding foreign filing licenses vary and may even conflict. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our intellectual property. In many 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 partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. For instance, a patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not necessarily extend to all patent claims, but instead only to patent claims that read on the product as approved. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition.

Given the amount of time required for the development, testing and regulatory review of our new product candidates such as GSBR-1290, ANPA-0073 and any of our future product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension) as compensation for effective patent term lost during product development and FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent

term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Further, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product candidates earlier than might otherwise be the case.

Intellectual property rights do not necessarily address all potential threats to our business.

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. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;
- we might not have been the first to file patent applications covering certain of the inventions we own or control;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process or technology export can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- pending patent applications that we own or control may not lead to issued patents;
- issued patents that we own or control may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other foreign countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the United States may have patent laws that are less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe 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.

Our product candidates and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technologies, including interference or derivation, PGR and IPR proceedings before the USPTO. 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. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technologies or product candidate, or redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. In addition, we could be found liable for monetary damages, including treble damages

and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Third parties asserting their patent or other intellectual property rights against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Additionally, during the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as 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 existing product candidates, 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 future products, which could have a material adverse effect on our business.

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

Competitors or other third parties may infringe or otherwise violate our patents, trademarks 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. Our pending patent applications cannot be enforced against third parties practicing the technologies claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or patent offices in foreign countries or made a misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, IPR, or PGR, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the

context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. There may be invalidating prior art, of which we and the patent examiner were unaware during prosecution. There may be double patenting among our own patents, which the patent examiner(s) fail to raise during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

In any 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 patents 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 patent claims do not cover the invention, or decide that the other party's use of our patented technologies falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or other 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. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade other companies from collaborating with us to license, develop or commercialize current or future product candidates. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. 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 whom we have asserted trademark infringement has superior rights to the marks in question. In such case, we could ultimately be forced to cease use of such trademarks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ADSs. Moreover, we cannot assure you 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. 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 could outweigh any benefit we receive as a result of the proceedings.

Further, interference or derivation proceedings provoked by third parties or brought by the USPTO or patent offices in foreign countries may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technologies or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technologies or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States and other foreign countries could increase uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our patents or narrow the scope of our patent protection. On September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) was signed into law. When implemented, the Leahy-Smith Act included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a patent claim invalid even though the same evidence would be insufficient to invalidate the patent claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, under the Leahy-Smith Act, the United States transitioned from a “first-to-invent” system to a “first-to-file” system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention

where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

The USPTO developed new regulations and procedures governing the administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. It remains unclear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a negative effect on our business.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and, further, may export otherwise infringing product candidates to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These product candidates may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation 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. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse.

Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have

compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed trade secrets or other confidential information of their current or former employers or claims asserting inventorship or ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other healthcare, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or client. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being invalid or unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. 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 our management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing product candidates and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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 executing 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 not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

Any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, may not be complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Also, our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of the claims of our patent applications or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we may not be the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a patent claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the Leahy-Smith Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

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 business may be adversely affected.

Our current or future trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. 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 may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

Risks Related to Our ADSs

The price of our ADSs may be volatile, and you could lose all or part of your investment.

The trading price of our ADSs is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report, these factors include:

- the commencement, enrollment or results of our ongoing and planned preclinical studies and clinical trials, or any future preclinical studies or clinical trials, we may conduct of our current and any future product candidates, or changes in the development status of our current and any future product candidates;
- any delay in preparing regulatory submissions to support development or commercialization of our current and any future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such submissions, including without limitation the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- adverse results or delays in our preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive marketing approval for our current and any future product candidates;
- changes in laws or regulations applicable to our current and any future product candidates, including but not limited to clinical trial requirements for approvals;
- the failure to obtain coverage and adequate reimbursement of our current and any future product candidates, if approved;
- changes on the structure of healthcare payment systems;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- our inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;

- our inability to establish collaborations if needed;
- our failure to commercialize our current and any future product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our current and any future product candidates;
- introduction of new products or services offered by us or our competitors, or the release or publication of clinical trial results from competing product candidates;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- issuances of debt or equity securities;
- sales of our ADSs by us or our shareholders in the future, or the perception that such sales may occur;
- trading volume of our ADSs;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or shareholder litigation;
- general geopolitical and macroeconomic conditions, including as a result of bank failures, global pandemics or the Russia/Ukraine conflict; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Although our annual financial statements were audited and reported upon by auditors who are currently subject to inspection by the Public Company Accounting Oversight Board ("PCAOB"), there is no guarantee that future audit reports will be prepared by auditors that are subject to inspection 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 ("HFCA Act") or the Accelerating Holding Foreign Companies Accountable Act ("AHFCA Act") if the SEC subsequently identifies that our audit work is performed by an auditor that the PCAOB is unable to inspect or investigate completely, and as a result, U.S. national securities exchanges, such as the Nasdaq, may delist our securities.

As part of a continued regulatory focus in the United States on access to audit and other information, the United States passed the HFCA Act in December 2020. The HFCA Act requires 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 HFCA Act also requires public companies identified by the SEC to certify that they are neither owned nor controlled by a foreign government, and make certain additional disclosures in their SEC filings.

The HFCA Act also provides that if an auditor of a U.S. listed company's financial statements is not subject for three consecutive "non-inspection years" after the HFCA Act becomes effective, the SEC must prohibit the securities of such issuer from being traded on a U.S. national securities exchange. However, in June 2021, the U.S. Senate passed the AHFCA Act which amends 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 subject to two "non-inspection years" instead of three. On February 4, 2022, the U.S. House of Representatives passed the America Creating Opportunities for Manufacturing, Pre-Eminence in Technology, and Economic Strength Act of 2022, which contained, among other things, an identical provision. In December 2021, the PCAOB issued a report on its determination that it is unable to inspect or investigate completely PCAOB-registered accounting firms headquartered in Mainland China and in Hong Kong. Also, in December 2021, the SEC adopted final amendments to its rules implementing the HFCA Act and established procedures to identify issuers and prohibit the trading of the securities of certain registrants as required by the HFCA Act. This rule stated that only the principal accountant, as defined by Rule 2-05 of Regulation S-X and PCAOB AS 1205, is "deemed 'retained' for purposes of Section 104(i) of the Sarbanes-Oxley Act and the Commission's determination of whether the registrant should be a Commission Identified Issuer." In December 2022, the PCAOB vacated its determination that it was unable to inspect and investigate PCAOB-registered public accounting firms in Mainland China and Hong Kong. As a result, until such time as the PCAOB issues a new determination, the SEC has determined that there are no issuers currently at risk of having their securities subject to a trading prohibition under the HFCA Act. However, while vacating those determinations, the PCAOB noted that, should it encounter any impediment to conducting an inspection or investigation of auditors in Mainland China or Hong Kong as a result of a position taken by any authority there, the PCAOB would act to immediately issue a new determination.

In May 2023, we dismissed PricewaterhouseCoopers LLP and engaged Ernst & Young LLP as our independent registered public accounting firm. Each of PricewaterhouseCoopers LLP and Ernst & Young LLP, is headquartered in the United States, is registered with the PCAOB and is an auditor of companies that are both registered with the SEC and publicly traded in the United States. As a result, the HFCA Act did not previously and does not currently apply to us. However, if our operations fundamentally change in a way that requires our independent registered public accounting firm to be located in China in order to comply with the standards of the PCAOB regarding auditors then the HFCA Act would apply to us. Such a restriction would negatively impact our ability to raise capital. We view the likelihood to be remote that our operations will fundamentally change, as to require our auditor to be located in China. Additionally, it is possible that in the future Congress could amend the HFCA Act or the SEC could modify its regulations to apply the restrictions, including trading prohibitions and delisting, under the HFCA Act in situations in which an independent

registered public accounting firm in China performs part of the audit such as in our current situation. There are currently no such proposals.

Further, 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, in the future, we will be able to comply with requirements imposed by U.S. regulators. 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 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.

We have identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or fail to maintain effective internal control over financial reporting, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.

We have identified material weaknesses in our internal control over financial reporting, which continue to exist as of June 30, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. These material weaknesses are as follows:

We did not design and maintain an effective control environment commensurate with our financial reporting requirements as we lacked a sufficient complement of professionals commensurate with our financial reporting requirements. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, amongst other things, insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses:

We did not design and maintain effective controls to ensure adequate segregation of duties within our financial reporting function, including controls related to the procurement and payroll processes, journal entries and account reconciliations. Specifically, certain personnel have incompatible duties including the ability to (i) generate and approve invoices and authorize disbursements; (ii) add employees or modify employee data in the payroll system and authorize payments; (iii) create and post manual journal entries without an independent review; and (iv) prepare and review account reconciliations.

We did not design and maintain effective controls over certain information technology (“IT”) general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that program and data changes are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel; and (iii) computer operations controls to ensure that processing of data and data backups and recovery are monitored.

These material weaknesses did not result in any material misstatements to the consolidated financial statements. These material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

We are working to remediate the material weaknesses as efficiently and effectively as possible and full remediation may go beyond December 31, 2023. At this time, we cannot provide an estimate of costs expected to be incurred in connection with implementing this remediation plan; however, these remediation measures will be time consuming, will result in us incurring significant costs, and will place significant demands on our financial and operational resources.

Although we have begun to implement measures to address the material weaknesses, the implementation of these measures may not fully address the material weaknesses and deficiencies in our internal control over financial reporting. Further, in the future we may determine that we have additional material weaknesses. Our failure to remediate the material weaknesses or failure to identify and address any other material weaknesses that may be identified in the future could result in material misstatements to our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our securities. See Part I. Item 4. “Controls and Procedures— Management’s Plan to Remediate the Material Weakness” of this Quarterly Report.

Our principal shareholders and management own a significant percentage of our voting securities and will be able to exert significant control over matters subject to shareholder approval.

As of June 30, 2023, our executive officers, directors, five percent shareholders and their affiliates beneficially owned approximately 46% of the voting power of our outstanding share capital. Therefore, these shareholders will have the ability to influence us through their ownership positions. These shareholders may be able to determine all matters requiring shareholder approval. For example, these shareholders, acting together, may be able to control 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. These shareholders’ interests may not always coincide with our corporate interests or the interests of other shareholders, and these shareholders may exercise their voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. This may prevent or discourage unsolicited acquisition proposals or offers for our ADSs that you may believe are in your best interest as a holder of our ADSs.

A significant portion of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. This could cause the market price of our ADSs to drop significantly, even if our business is doing well.

Sales of a substantial number of our ADSs in the public market could occur at any time. If our shareholders sell, or the market perceives that our shareholders intend to sell, substantial amounts of our ADSs in the public market, the market price of our ADSs could decline significantly.

Beginning August 2, 2023, 77,745,193 ordinary shares (excluding the 18,000,000 ordinary shares issued to our depositary bank for bulk issuance of ADSs reserved for future issuances upon the exercise or vesting of awards granted under our equity incentive plans are available for sale in the public market, following the expiration of lock-up agreements entered into by substantially all of our shareholders in connection with the IPO. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of restrictions in the lock-up agreements, could cause the market price of our ADSs to fall or make it more difficult for our securityholders to sell their ADSs at a time and price that they deem appropriate.

In addition, promptly following the completion of our IPO, we filed a registration statement registering the issuance of approximately 22,099,376 ordinary shares (which may be in the form of ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares (or ADSs) registered under this registration statement are available for sale in the public market subject to

vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Additionally, the holders of an aggregate of 67,018,087 of our ordinary shares (including non-voting ordinary shares), or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares (or ADSs representing such shares) or to include their shares (or ADSs representing such shares) in registration statements that we may file for ourselves or other shareholders. If we were to register the resale of these shares or ADSs, they could be freely sold in the public market. If these additional shares or ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

Holders of our ADSs have fewer rights than our 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 their voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Holders of the ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. When a general meeting is convened, if you hold ADSs, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. We will take all commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. 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. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

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 plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement, our ordinary shares or the ADSs or the transactions contemplated thereby, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court in New York, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement, our ordinary shares and the ADSs and the transactions contemplated thereby. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based on a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement, our ordinary shares or the ADSs or the transactions contemplated thereby. 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 any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a

claim against us or the depositary in connection with matters arising under the deposit agreement, our ordinary shares or the ADSs or the transactions contemplated thereby, you or such other 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/or the depositary. If a lawsuit is brought against us and/or 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 augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

You may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

Although we do not have any present plans to declare or pay any dividends on our ordinary shares, in the event we declare and pay any dividends, the depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to register under U.S. securities laws any offering of ADSs, ordinary shares or other securities received through such distributions. We also have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have an adverse effect on the value of your ADSs.

Your right to participate in any future rights offerings may be limited, which may cause dilution to your 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 you 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 bank will not make rights available to you unless the rights and any related securities are registered under the Securities Act or are otherwise 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, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

Because we do not anticipate paying any cash dividends on our ADSs in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our ADSs to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, including that our company may only pay dividends out of profits or out of the credit standing in our share premium account, and provided always that in no circumstances may a dividend be paid if it would result in our inability to pay our debts as they fall due in the ordinary course of business. In addition, our shareholders may, subject to our memorandum and articles of association, by ordinary resolution declare a dividend, but no

dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our ADSs will be your sole source of gains for the foreseeable future.

We are subject to tax in the Cayman Islands and the United States.

We are a Cayman Islands corporation as of the date of this Quarterly Report. We are treated as an exempted company for Cayman Islands tax purposes. We are also treated as a U.S. corporation subject to U.S. federal income tax pursuant to Section 7874 of the Code, and are subject to U.S. federal income tax on our worldwide income. As a result, we are subject to tax both in the Cayman Islands and the United States, which could have a material adverse effect on our financial condition and results of operations.

It is unlikely that we will pay any dividends on our ordinary shares or ADSs in the foreseeable future. However, dividends received by “non-U.S. holders” will be subject to U.S. withholding tax. In addition, because the ordinary shares or ADSs are treated as shares of a U.S. domestic corporation, the U.S. gift, estate and generation-skipping transfer tax rules generally apply to a non-U.S. holder of ordinary shares or ADSs.

Each holder or prospective holder of our ordinary shares or ADSs should seek tax advice from an independent tax advisor based on such holder’s particular circumstances.

Our ability to use our NOLs carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had $66.4 million of U.S. federal NOLs and $74.6 million of state NOLs. U.S. federal NOL carryforwards totaling $66.4 million can be carried forward indefinitely under current law. State NOL carryforwards totaling $74.6 million will begin to expire in 2037, unless previously utilized. As of December 31, 2022, we also had aggregate U.S. federal and state R&D credits of approximately $0.6 million and $0.3 million, respectively. U.S. federal R&D credits carryforwards begin to expire in 2029 unless previously utilized. The state R&D credit carryforwards do not expire. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards, R&D credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. We have not undertaken a study under Section 382 of the Code, and it is possible that we have previously undergone one or more ownership changes so that our use of NOLs is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our share ownership, including as a result of our IPO. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We will incur significantly increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company in the United States, we will incur significant legal, accounting and other expenses that we did not incur previously. These expenses will likely be even more significant after we no longer qualify as an emerging growth company and/or a smaller reporting company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), the listing requirements of 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act, beginning with our Annual Report on Form 10-K for the year ended December 31, 2023, we will be required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an emerging growth company or a smaller reporting company with less than $100 million in annual revenues, we will not be required to include an attestation report on internal controls over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we will be 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, potentially 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, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal controls over financial reporting is effective as required by Section 404.

We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our ADSs less attractive to investors.

We are an "emerging growth company", as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until December 31, 2028, the last day of the fiscal year ending after the fifth anniversary of our IPO or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross

revenues equal or exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period prior to such time. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with certain new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

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 and will be able to take advantage of these scaled disclosures for so long as our ADSs held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our ADSs held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Since shareholder rights under Cayman Islands law differ from those under U.S. law, you may have difficulty protecting your shareholder rights.

We are an exempted company limited by shares incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our memorandum and articles of association, 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 our directors, actions by our minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, 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 laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records, other than the memorandum and articles of association and any special resolutions passed by such companies, and the registers of mortgages and charges of such companies. The Registrar of Companies of the Cayman Islands shall make available the list of the names of the current directors of the Company (and where applicable the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. Our directors have discretion under our post-offering memorandum and 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 you 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.

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. Currently, we do not plan to rely on home country practice with respect to any corporate governance matter. However, if we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

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 our management, members of our board of directors or our controlling shareholders than they would as public shareholders of a company incorporated in the United States.

Provisions in our amended and restated memorandum and articles of association may prevent or frustrate attempts by our shareholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our ADSs may be lower as a result.

There are provisions in our amended and restated memorandum and articles of association that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other shareholders. For example, as of the date of this Quarterly Report, our board of directors will have the authority to issue up to 92,589,482 shares of an additional class or classes of shares, which could include preference shares. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the other classes of shares without any further vote or action by our shareholders. The issuance of such shares may delay or prevent a change of control transaction. As a result, the market price of our ADSs and the voting and other rights of our shareholders may be adversely affected. An issuance of other classes of shares may result in the loss of voting control to other shareholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- shareholders will be entitled to remove directors only for cause;
- shareholders will not be permitted to take actions by written consent; and
- shareholders must give advance notice to nominate directors or submit proposals for consideration at annual general meetings.

These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our ADSs.

You may be subject to limitations on transfers of your ADSs.

Your 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 deemed necessary or advisable by it in good faith in connection with the performance of its duties or at our reasonable written request, subject in all cases to compliance with applicable U.S. securities laws. 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.

General Risk Factors

We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public

companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Act was enacted and included significant corporate governance and executive compensation related provisions that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of Nasdaq, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with the year ending December 31, 2023, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our annual report for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to our IPO, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. We expect that we will need to implement a new internal system to combine and streamline the management of our financial, accounting, human resources and other functions. However, such a system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent

limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information, the market price of our ADSs could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

As a public company, beginning with our Annual Report on Form 10-K for the year ending December 31, 2023, we will be subject to the requirements of Section 404 of the Sarbanes-Oxley Act, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably ensure that information we must disclose in reports we file or submit pursuant to the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See Part I. Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements” of this Quarterly Report.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our ADSs could decline.

The trading market for our ADSs will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our ADSs, and such lack of research coverage may adversely affect the market price of our ADSs. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our ADSs could decline if one or more equity research analysts downgrade our ADSs or issue other unfavorable commentary or research about us. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which in turn could cause the trading price or trading volume of our ADSs to decline.

We could be subject to securities class action litigation.

In the past, 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 pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our headquarters and main research facility are located near San Francisco, California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

If we fail to comply with 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, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our ADSs.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our ADSs. Such a delisting would likely have a negative effect on the price of our ADSs and would impair your ability to sell or purchase our ADSs when you wish to do so. In the event of a delisting, any action taken by us to restore compliance with listing requirements may not allow our ADSs to become listed again, stabilize the market price or improve the liquidity of our ADSs, prevent our ADSs from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

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

On February 2, 2023, the registration statement on Form S-1 (Registration No. 333-269200) for our IPO of our ADSs was declared effective by the SEC. On February 7, 2023, we closed our IPO and 12,351,000 ADSs, each representing three ordinary shares, were issued and sold at a public offering price of $15.00 per ADS (including the underwriters' exercise in full of their option to purchase up to 1,611,000 additional ADSs). We raised approximately $185.3 million in aggregate offering proceeds.

Jefferies LLC, SVB Securities LLC, Guggenheim Securities, LLC, and BMO Capital Markets Corp. acted as representatives of the underwriters for the offering. We compensated the underwriters of our IPO underwriting discounts and commissions totaling $13.0 million and incurred approximately $5.6 million in estimated offering costs, thus our net offering proceeds, after deducting underwriting discounts and commissions and estimated offering expenses, were approximately $166.7 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC on February 6, 2023 pursuant to Rule 424(b)(4).

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description of Document	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Memorandum and Articles of Association of the registrant.	8-K	001-41608	3.1	February 7, 2023	
4.1	Registrant's Specimen Certificate for Ordinary Shares.	S-1/A	333-269200	4.1	January 30, 2023	
4.2	Form of Deposit Agreement.	S-1/A	333-	4.2	January 30,	
4.3	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 4.2).	S-1/A	333-269200	4.3	January 30, 2023	
4.4	Amended and Restated Investors' Rights Agreement, dated July 30, 2021, by and between the registrant and the investors named therein.	S-1	333-269200	4.4	January 12, 2023	
4.5	Summary of Rights of Non-Voting Ordinary Shares.	10-Q	001-41608	4.5	May 11, 2023	
10.1	Exchange Agreement dated May 10, 2023 between the registrant and the investors named therein.	10-Q	001-41608	10.1	May 11, 2023	
10.2	Lease Agreement, dated June 29, 2023, by and between the registrant and Shanghai Changtai Business Management Co., Ltd.	8-K	001-41608	10.1	July 6, 2023	
10.3	House Leasing Contract, dated June 29, 2023, by and between the Shanghai ShouTi Biotechnology Co., ltd. and Shanghai Chuangzhi Space Entrepreneurship Incubator Management Co., Ltd.	8-K	001-41608	10.2	July 6, 2023	
10.4	Sublease, dated June 29, 2023, by and between Structure Therapeutics USA Inc. and Aligos Therapeutics, Inc.	8-K	001-41608	10.3	July 6, 2023	
10.5	Non-employee Director Compensation Policy.	8-K	001-41608	10.1	August 4, 2023	

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.	X
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.	X
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.	X
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.	X
101.INS	Inline XBRL Instance Document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

^ The certifications attached as Exhibits 32.1 and 32.2 accompanying this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Company under the Securities Act or the Exchange Act whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained 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.

Date: November 16, 2023

STRUCTURE THERAPEUTICS INC.

By: /s/ Raymond Stevens, Ph.D.

Raymond Stevens, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Jun Yoon

Jun Yoon
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION 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, Raymond Stevens, Ph.D., certify that:

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

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];

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

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

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

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

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

Date: November 16, 2023

By: /s/ Raymond Stevens

Raymond Stevens, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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, Jun Yoon, certify that:

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

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];

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

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

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

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

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

Date: November 16 2023

By: /s/ Jun Yoon

Jun Yoon
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 of Structure Therapeutics Inc. (the "Company") on Form 10-Q/A for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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, as amended; and

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

Date: November 16, 2023

By: /s/ Raymond Stevens

Raymond Stevens, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 of Structure Therapeutics Inc. (the "Company") on Form 10-Q/A for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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, as amended; and

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

Date: November 16, 2023

By: /s/ Jun Yoon

Jun Yoon
Chief Financial Officer
(Principal Financial and
Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.