

REFINITIV

DELTA REPORT

10-K

STRUCTURE THERAPEUTICS IN
10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	6380
CHANGES	236
DELETIONS	3975
ADDITIONS	2169

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

FORM 10-K

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

For the fiscal year ended ~~December 31, 2022~~ December 31, 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.)

611 601 Gateway Blvd., Suite 223 900

South San Francisco, California
(Address of principal executive offices)

94080
(Zip code)

Registrant's telephone number, including area code: ~~(628) 229-9277~~ (650) 457-1978

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 share*	GPCR	Nasdaq Global Market
		Nasdaq Global Market*

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 232.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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 market value of the registrant's ordinary shares held by non-affiliates of the registrant was not a public company as of June 30, 2023, the last business day of its the registrant's most recently completed second fiscal quarter, and, therefore, cannot calculate was approximately \$501.7 million, based on the aggregate closing price of the registrant's ordinary shares represented by ADSs on the Nasdaq Global Market of \$41.57 per ADS. In determining the market value of its the voting equity held by non-affiliates, as ordinary shares of such date, the registrant beneficially owned by each director and officer and each person who owns 10% or more of the registrant's outstanding ordinary shares have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding ordinary shares of the registrant, par value \$0.0001 per share, as of March 15, 2023 February 29, 2024 was 114,729,529 139,794,124, of which 12,351,000 129,882,333 ordinary shares were held in the form of ADSs.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 Annual General Meeting of Shareholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

[Table of Contents](#)

TABLE OF CONTENTS

	Page
Part I	
Item 1. Business	6
Item 1A. Risk Factors	68 67
Item 1B. Unresolved Staff Comments	149 147
Item 1C. Cybersecurity	147
Item 2. Properties	149 148
Item 3. Legal Proceedings	149 148
Item 4. Mine Safety Disclosures	149
Part II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	149
Item 6. [Reserved]	158
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	159
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	172 170
Item 8. Financial Statements and Supplementary Data	174 171
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	206 205
Item 9A. Controls and Procedures	206 205
Item 9B. Other Information	208 207
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	208 207
Part III	
Item 10. Directors, Executive Officers and Corporate Governance	208
Item 11. Executive Compensation	215 208
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	223 208
Item 13. Certain Relationships and Related Transactions, and Director Independence	226 208
Item 14. Principal Accounting Accountant Fees and Services	231 208
Part IV	
Item 15. Exhibits, Financial Statement Schedules	231 209
Item 16. Form 10-K Summary	236 214
Signatures	236 215

[Table of Contents](#)

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report"), contains forward-looking statements. All statements other than statements of historical facts contained in this Annual 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 Annual 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 impact of data collection omissions at any of our clinical sites;
- 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 the COVID-19 pandemic geopolitical and other macroeconomic factors.

The forward-looking statements in this Annual 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

3

Table of Contents

condition, results of operations, business strategy, short-term and long-term business operations and

3

Table of Contents

objectives, and financial needs. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of known and unknown risks, uncertainties, and assumptions, including those described under Part I. Item 1A. "Risk Factors" and Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual 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 Annual 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 Annual report relate only to events or information as of the date on which the statements are made in this Annual 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 Annual 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 I. Item 1A. "Risk Factors" in this Annual 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, GSB-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.

4

[Table of Contents](#)

- 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 ("SAEs"), 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 GSB-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 We have experienced delays due to actions of third parties in the past and if in the future 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 collaborations with Schrödinger, Inc. ("Schrö LLC (together with its affiliates, "Schrödinger") is are important to our business. If we are unable to maintain this collaboration, these collaborations, or if this collaboration is these collaborations are 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.

5

[Table of Contents](#)

- 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

5

[Table of Contents](#)

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.

- Our business and the business or operations of third parties with whom we conduct business has been and could continue to be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have business operations.
- 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

Item 1. Business.

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 **needs, 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 **approximately \$166.7 million**, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. **In September 2023, we entered into a share purchase agreement with certain institutional investors (the "Purchase Agreement"), pursuant to which we issued and sold an aggregate of 21,617,295 ordinary shares and 2,401,920 non-voting ordinary shares for net proceeds of approximately \$281.5 million (the "Private Placement").**

Our initial focus is on **G-protein-coupled 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 GSB-1290, our oral small molecule product candidate targeting the validated glucagon-like-peptide-1 receptor ("GLP-1R") for the treatment of **type-2 type 2** diabetes mellitus ("T2DM") and obesity. We completed our Phase 1 single ascending dose ("SAD") study of GSB-1290 in September 2022. GSB-1290 was generally well tolerated and demonstrated **dose-dependent pharmacokinetics dose- dependent pharmacokinetic** ("PK") and **pharmacological pharmacodynamic** ("PD") activity. We submitted an **Investigational New Drug application investigational new drug** ("IND") **application to the United States Food and Drug Administration ("FDA") 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 of

6

[Table of Contents](#)

GSB-1290 in January 2023 and completed dosing in **otherwise** healthy overweight subjects

6

[Table of Contents](#)

in March 2023. **We plan to submit In May 2023, we submitted** a protocol amendment to the FDA **to transition to a** and initiated dosing of the Phase 2a proof-of-concept study in T2DM and **obesity. We reported topline data for the 28-day Phase 1b MAD study in September 2023, in which GSB-1290 was generally well-tolerated with no adverse event ("AE")-related discontinuations and demonstrated an encouraging safety profile and significant weight loss of up to 4.9% placebo-adjusted, supporting once-daily dosing. In December 2023, we reported clinically meaningful topline data from our Phase 2a T2DM cohort, interim results from our Phase 2a obesity cohort and topline data from a Japanese ethno-bridging study of GSB-1290. These data demonstrated that GSB-1290 was generally well-tolerated, with no treatment-related SAEs**

over 12 weeks, with only one participant discontinuing the expected initiation study due to adverse events in the T2DM cohort and none in the obesity cohort. GSBR-1290 also showed significant reductions in weight in the obesity cohort at 8 weeks, and significant reductions in hemoglobin A1c ("HbA1c") and weight in the T2DM cohort. We expect to report the full 12-week Phase 2a obesity data in the latter half of the second quarter of 2024 with additional 24 participant data. We also fully enrolled a formulation bridging and titration optimization study to evaluate capsule versus tablet PK and explore different titration regimens of GSBR-1290. We expect to report topline results from this study in the latter half of the second quarter of 2024, in preparation for the global Phase 2b study for obesity which we expect to initiate in the second half of 2023. We expect to report topline data 2024. A Phase 2 study in T2DM is also planned for the Phase 1b study and Phase 2a study in the second half fourth quarter of 2023. Beyond GSBR-1290, we are developing next generation GLP-1R candidates, including dual GLP-1R/GIPR agonists, each designed with customized properties to achieve additional benefit. In September 2022, we completed a Phase 1 SAD and MAD study evaluating ANPA-0073, our small molecule product candidate targeting the apelin receptor ("APJR") in which it 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.

A number of GPCR properties contribute to its importance as a drug target class, including interaction with a diverse set of signaling molecules, involvement in a vast array of physiological and pathological processes, and cell surface expression that enables extracellular drug binding. As such, GPCRs have emerged as the largest family of targets for approved drugs, have provided significant benefit to patients and have achieved blockbuster sales in a number of therapeutic indications, including diabetes (Victoza), bipolar disorders (Abilify, Seroquel), asthma (Singulair), hypertension (Diovan, Lopressor), and cardiovascular disease (Plavix). Despite this success, there remain a number of challenges to continued innovation in this target class, including (i) low expression levels on cell surfaces, (ii) the complexity of the multi-subunit peptide GPCR receptor, (iii) difficulties in obtaining relevant crystal structures as a basis for drug design, and (iv) non-specific signaling through multiple intracellular signaling pathways, a concept known as non-biased signaling, which can limit activity and increase side effects. We have developed a platform designed to address these key challenges, enabling us to discover small molecule drugs to effectively target GPCRs. Further, our platform has been designed to develop novel drugs against other targets where traditional drug discovery methods have not been adequate.

Our next generation structure-based drug discovery platform is based on techniques that our founders have evolved for over 25 years, which enables us to generate small molecule product candidates designed to overcome the historical limitations of GPCR drug development. As shown below, we believe our insights and capability to visualize the three-dimensional protein structures of the target and the ligands combined with the computational chemistry capabilities of our co-founder and strategic partner, Schrödinger, give us significant competitive advantages in highly efficient and rational drug design. We design our novel compounds by combining our knowledge of GPCR structures together with advanced physics-based computational methods, which we believe allows us to predict the binding affinity of molecules to the target site with a high degree of accuracy.

[Table of Contents](#)

Advantages of GPCR oral small molecule therapeutic



Graphic

CHALLENGES

- Limited cellular and tissue permeability
- Generally not orally available Scalability and costs
- Limited stability cold supply chain requirements
- Cold supply chain requirements
- Higher costs

OPPORTUNITIES

- Customizable pharmaceutical properties
- Orally available, better patient compliance
- No cold-chain requirements
- Lower costs
- Lower costs Large scale manufacturing capability

We believe the strengths of our platform position us to develop oral small molecule drugs that can deliver biologic-like activity and specificity. Oral small molecules can address many of the key limitations of biologic and peptide drugs, thereby significantly improving patient access. We believe this is particularly important for the most prevalent chronic diseases including those involving the metabolic, cardiovascular, and pulmonary systems.

Our lead product candidate, GSBR-1290, is an oral and biased small molecule agonist of GLP-1R, a validated GPCR drug target for T2DM and obesity. obesity, currently in Phase 2 development. There are currently five ten marketed peptide molecules that target GLP-1R; collectively, these peptide therapies generated worldwide sales of \$13.2 \$65 billion in 2020, 2023. However, there are currently no approved oral small molecule therapies targeting GLP-1R. In non-human primate ("NHP"), studies, GSBR-1290 demonstrated glucose-dependent insulin secretion and suppressed food intake, resulting in weight reduction. Given these findings and other compelling preclinical data, we completed a Phase 1 study in healthy volunteers for GSBR-1290 in September 2022. GSBR-1290 was generally well tolerated and demonstrated dose-dependent PK and PD related activity. We submitted an IND to the 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 MAD study in January 2023 and completed dosing in healthy overweight subjects in March 2023. We plan to submit a protocol amendment to the FDA to transition to 2022, a Phase 2a proof-of-concept study development in T2DM diabetes in December 2023 and obesity with the expected initiation in the second half of 2023. We expect to report topline data for the Phase 1b study and complete a Phase 2a study in obesity in the latter half of the second half quarter of 2023, 2024. To date GSBR-1290 has demonstrated generally favorable safety, tolerability and efficacy results in clinical trials. Beyond GSBR-1290, we are developing next generation GLP-1R candidates, including dual GLP-1R/GIPR glucose-dependent insulinotropic polypeptide receptor ("GIPR") agonists and amylin agonists, each designed with customized properties to achieve additional benefit.

8

[Table of Contents](#)

We are also developing oral small molecule therapeutics targeting other GPCRs for the treatment of pulmonary and cardiovascular diseases. Specifically, we are advancing ANPA-0073, our biased agonist, targeting the apelin receptor ("APJR,") a GPCR that has been implicated in IPF and PAH. idiopathic pulmonary fibrosis ("IPF"). In September 2022, we completed a Phase 1 SAD and MAD study evaluating ANPA-0073 in healthy human volunteers, in which it was generally well tolerated. Additionally, we are developing an antagonist that targets

LPA1R, lysophosphatidic acid 1 receptor ("LPA1R"), a GPCR implicated in responses to tissue injury and pro-fibrotic processes. We have demonstrated substantial anti-fibrotic activity of our LPA1R antagonists in mouse models of fibrotic lung disease and we selected a development candidate, (LTSE-2578) LTSE-2578, in January 2023 and expect to initiate a first-in-human study in the second quarter of 2024.

At Basecamp Bio Inc. ("Basecamp Bio"), our wholly owned subsidiary We are also dedicated to fueling our pipeline and pursuing drug discovery partnerships, partnerships. Through our discovery engine, we leverage the power of cryo-electron microscopy ("cryo-EM") machine learning and X-ray crystallography, as the basis for our molecular designs. We employ state-of-the-

[Table of Contents](#)

art state-of-the-art small molecule hit identification, including DNA encoded library technology and affinity mass spectrometry selections for membrane proteins.

Our Strategy

Our mission is to discover and develop broadly accessible oral therapeutics to treat a wide range of chronic diseases with unmet medical need through advancements in structure-based drug discovery and computational chemistry. The key pillars of our business strategy to achieve this mission include:

- **Invest in and leverage our next generation structure-based drug discovery platform to drive innovations in GPCR targeted therapies and beyond.** Our platform has the potential to transform the treatment paradigm for a wide range of chronic diseases with unmet medical need. We are continually growing our position as a leader in structure-based drug discovery and development by incorporating platform innovations that have the potential to expand the therapeutic opportunity of this field. We are integrating advancements in computational chemistry, molecular imaging technologies, structural biology techniques, and machine learning while continuing to deepen our understanding of GPCR signaling pathways and pharmacology. We intend to expand into other key emerging areas where we can leverage our platform to develop orally-available molecules against targets that historically have been limited to peptides or biologics.
- **Advance our GLP-1R franchise of metabolic focused assets, establishing a foundation for additional opportunities.** Our franchise approach involves developing next generation GLP-1R agonists, including dual GLP-1R/GIPR agonists, each designed with customized properties to achieve maximum benefit. Based on compelling data generated from our preclinical studies, we believe that our lead GLP-1R candidate, GSB-1290, has the potential to be a differentiated treatment for T2DM and obesity. In obesity, we expect to complete the Phase 2a study in the latter half of the second quarter of 2024 and we completed initiate a Phase 1 SAD 2b study in September 2022. We initiated the fourth quarter of 2024. In T2DM, we have completed the Phase 1b MAD 2a study in January 2023 and completed dosing in healthy overweight subjects in March 2023. We plan expect to submit a protocol amendment to the FDA to transition to initiate a Phase 2a proof-of-concept 2 study in T2DM and obesity with the expected initiation in the second half of 2023, 2024. In addition, our next generation GLP-1R program is focused on the development of orally-available small molecules in combination with GLP-1R, and glucose-dependent insulinotropic polypeptide receptor ("GIPR") activity, including GIPR, amylin, as well as the APJR for selective or muscle-sparing weight loss.
- **Pursue additional opportunities in chronic diseases.** Chronic diseases pose a major burden to patients and healthcare systems worldwide and there is an urgent need for effective and more accessible treatment options. For our Our APJR agonist product candidate, ANPA-0073, we completed a Phase 1 SAD and MAD study in healthy human volunteers in September 2022. ANPA-0073 is in development for the treatment of patients with IPF cardiopulmonary and PAH. We expect to conduct additional preclinical studies to be followed by a Phase 1 formulation bridging PK study in Australia, cardiometabolic conditions. In addition, we are evaluating LPA1R antagonism in IPF, and selected a development candidate (LTSE-2578) in January 2023 and expect to initiate a first-in-human study in the second quarter of 2024. We plan to continue to harness insights on GPCR targets, particularly among metabolic, endocrine, pulmonary, and cardiovascular indications, and leverage our platform to fuel our pipeline through our discovery engine at Basecamp Bio. Bio Inc. ("Basecamp Bio").

[Table of Contents](#)

- **Maximize the potential of our platform and portfolio through strategic partnerships.** We have an established value- and capability-enhancing collaboration collaborations with Schrödinger, our co-founder and strategic partner. We intend to continue to explore additional collaborations with third parties to further strengthen our platform capabilities and enable expansion of our portfolio. We plan to leverage our platform for external opportunities where partners bring additional disease biology understanding, drug development and commercial expertise, regional insights, or other complementary capabilities.

Our Pipeline and Programs

We pursue opportunities to target GPCRs in human diseases on the basis of validated biology, safety, development feasibility and market potential. We are building a pipeline of wholly-owned oral small molecule

9

Table of Contents

drugs targeting chronic diseases with unmet medical need and commercial potential. Our initial focus is in areas of metabolic, cardiovascular and pulmonary diseases.

The following table summarizes key information on our current product candidates:



Graphic

Metabolic Diseases

We are initially advancing our GLP-1R franchise as a treatment for T2DM obesity and obesity, T2DM, conditions affecting approximately 537.64 million and 764 million 537 million people worldwide, respectively. We believe our GLP-1R programs have demonstrated qualities that offer the potential to differentiate them versus from current approved and in development stage programs.

- **GSBR-1290, Selective GLP-1R Program.** GSBR-1290 is a biased GLP-1R agonist which has demonstrated dose-dependent activation of the G-protein pathway. GSBR-1290 has also demonstrated glucose-dependent insulin secretion and suppressed food intake with similar activity to an approved injectable peptide GLP-1R agonist in preclinical models. The product candidate is designed to be orally administered, without restrictions on diet or concomitant therapy. We submitted an IND in the United States for our dose escalation Phase 1b study in T2DM and obesity. In September 2022, we received FDA allowance to proceed with the Phase 1b MAD study, which we initiated in January 2023, and completed dosing in March 2023. We plan to submit a protocol amendment to the FDA to transition to a Phase 2a proof-of-concept study in T2DM and obesity with the expected initiation in the second half of 2023. We expect to report topline data for the Phase 1b study and Phase 2a study in the second half of 2023. We will initially focus development of GSBR-1290 on T2DM with a secondary focus on obesity therapy.
- **Next generation GLP-1R Combination.** Our combination and next generation small molecule program is focused on GLP-1R candidates, including GLP-1R/GIPR modulation agonists and amylin agonists, each designed with the potential customized properties to achieve additional benefits like enhanced metabolic control. Our APJR agonist, ANPA-0073, is being evaluated for enhanced metabolic control, selective or muscle-sparing weight loss. ANPA-0073, is a G-protein biased APJR agonist for which we completed a Phase 1 SAD and MAD study, in which it was generally well tolerated as a single dose from 2mg to 600 mg, and at doses from 75 mg to 500 mg once daily dosing for seven days, with no SAEs reported.

[Table of Contents](#)

Pulmonary and Cardiovascular Diseases

Our APJR agonist We are evaluating our LPA1R program, is being evaluated LTSE-2578 for IPF and PAH. In another program, we are evaluating LTSE-2578 for IPF, PPF.

Our APJR product candidate, ANPA-0073, LPA1R program, LTSE-2578, is an investigational oral small molecule LPA1R antagonist. We believe LTSE-2578 is a G-protein biased APJR agonist for which we completed differentiated molecule because it demonstrated potent in vitro and in vivo activity in preclinical IPF models and dose dependent inhibition of histamine release as the PD marker. We plan to initiate a Phase 1 SAD and MAD first-in-human study in which it was generally well tolerated as a single dose from 2mg to 600 mg, and at doses from 75 mg to 500 mg once daily dosing for seven days, with no serious adverse events ("SAEs") reported, the second quarter of 2024.

GPCRs as a Therapeutic Target Family

GPCRs form the largest human membrane protein family, consisting of approximately 800 identified members as illustrated below. GPCRs are involved in several vital physiological functions, such as immune system

[Table of Contents](#)

regulation and inflammation, autonomic nervous system transmission, behavioral and mood regulation, sensory transmission, and maintenance of homeostasis, making them important targets for numerous therapeutics. To date, there are approximately 475 drugs on the market acting at over 100 unique GPCRs. Additionally, more than 220 GPCRs have not yet been explored as clinical targets, hence representing broad untapped therapeutic potential for addressing global healthcare needs.

Phylogenetic tree of GPCR targets



Graphic

GPCR targeting drugs have successfully delivered significant patient benefit resulting in large market opportunities in many therapeutic areas. Examples include liraglutide (Victoza for T2DM), aripiprazole (Abilify for schizophrenia, bipolar disorder and depression), montelukast (Singulair for asthma), valsartan (Diovan for hypertension), metoprolol (Lopressor for hypertension, angina, and myocardial infarction), and clopidogrel (Plavix for myocardial infarction and stroke). GPCR related drugs are the largest drug class accounting for approximately 27% of global pharmaceutical sales with estimated aggregate sales of \$890 billion between 2011 and 2015.

11

[Table of Contents](#)

GPCRs are proteins that span the entire width of cell membranes. Their primary function is to recognize extracellular substances, primarily ligands, and transmit signals across the cell membrane to the inside of the cell.

11

[Table of Contents](#)

Schematic of a GPCR



Graphic

As shown above, the binding of extracellular ligands to GPCRs elicits conformational changes that impact the intracellular side of the receptor, resulting in the formation of a GPCR complex with signal transducers, particularly G-proteins. These signal transducers go on to interact with second messengers, ultimately either stimulating or inhibiting certain cellular processes.

GPCRs signal not only through G-proteins, but also through β -arrestins and other non-G-protein transducers. β -arrestins play an essential role in many physiological and pathological processes, and are involved in the desensitization, internalization, sequestration, and trafficking of GPCRs. Certain GPCR ligands are capable of simultaneously activating both G-protein and non-G-protein mediated signaling pathways, which can lead to a variety of physiologic as well as pathologic effects.

Challenges of GPCR Therapeutic Discovery and Development

Despite tremendous advancements in structure-based drug design and development, GPCR drug discovery and development remains challenging.

- **Similarity between the binding sites of GPCRs and related receptors can cause off-target toxicities:** All GPCRs have the same overall three-dimensional architecture but the specific endogenous binding site is unique due to the placement of amino acid side chains shaping the binding site. For instance, the early sphingosine-1-phosphate 1 receptor ("S1P1R") agonist Gilenya led to the development of a new class of therapy for the treatment of multiple sclerosis, but had exhibited bradycardia as a side effect due in part to sphingosine-1-phosphate 3 receptor ("S1P3R") activity, a very closely related S1P1 receptor subtype. The next generation S1P1R agonist Zeposia was designed using structural information by Receptos, Inc. to remove the S1P3 and other activities and therefore did not have the same side effect profile as Gilenya.
- **GPCRs are involved in diverse downstream signaling pathways which can result in side effects:** GPCRs interact with a range of molecules, including G-protein and non-G-protein

12

[Table of Contents](#)

transducers including β -arrestin. Signaling pathway selectivity results from agonist-induced specific receptor conformation and when targeting GPCRs involved in multiple signaling pathways, both therapeutic benefits and side effect issues may arise.

12

[Table of Contents](#)

- **Expression levels of GPCRs are low and create significant hurdles to structural and PD characterization:** Recombinant protein expression of GPCRs remains extremely challenging. Expression levels of GPCRs are low and improvement of expression level continues to be mainly empirical and resource-consuming. GPCRs are complex membrane proteins that require a stable membrane environment throughout the purification process to avoid destabilization and aggregation.
- **GPCR structural visualization is complex making GPCR structure-based drug discovery challenging:** Structure-based drug design requires rapid iterations of GPCR structures in complex with specific new ligands to determine their effects on conformation. This is well established through robust crystallography platforms for soluble drug targets. Cryo-EM has helped accelerate the membrane protein field, but the methods still require substantial expertise and execution.

Drug discovery approaches targeting GPCRs have evolved from traditional approaches including high throughput screening to rational design for enhanced activity, tailor-made signaling response, and improved selectivity, which leads to improved safety and tolerability profiles.

Our Platform and Approach

Our platform is based on techniques that our founders have been evolving for over 25 years, which have enabled them to deliver multiple marketed medicines. Our approach enables us to generate small molecule product candidates that are designed to overcome the historical limitations of GPCR drug development.

Our insights and capabilities enable us to visualize the three-dimensional protein structures of the target and the ligands. We believe this visualization combined with the computational chemistry capabilities of Schrödinger gives us significant competitive advantages in highly efficient and rational drug design. We design our novel compounds by combining our knowledge of GPCR structures together with advanced physics-based computational methods, which we believe allows us to predict the binding affinity of molecules to the target site with a high degree of accuracy.

As shown below, our technology platform allows us to determine feasibility, optimize the design of, and efficiently generate families of potent and highly selective small molecule candidates.

13

[Table of Contents](#)

Structure Therapeutics integrated technology platform from target to IND



Graphic

13

[Table of Contents](#)

Oral small molecules have the potential to address the key limitations of biologic and peptide drugs, such as high cost and patient inconvenience, thereby significantly improving patient access. We believe this is particularly important for the most prevalent chronic diseases including those involving the endocrine, cardiovascular, and pulmonary systems. We believe the strengths of our technology platform will enable us to develop oral small molecule drugs that can deliver biologic-like activity and specificity.

Strategic GPCR Target Prioritization

We start with target prioritization by focusing on validated GPCR targets that do not have attractive small molecule solutions. We then prioritize by assessing the feasibility of a small molecule solution for these targets and market opportunities of their respective target indication.

Expertise in GPCR Structure-Based Drug Discovery

GPCRs are difficult to characterize structurally because they are composed of seven transmembrane domains, have low expression, and are unstable outside of the cell membrane environment. While structure-based approaches have been utilized for decades in soluble protein drug discovery, recent breakthrough advancements in computational chemistry, artificial intelligence, machine learning and electron microscopy are redefining the field of GPCR structure-based drug discovery.

14

[Table of Contents](#)

Visualization of GPCR Structure and binding site interactions



Graphic

As shown above, our structure-based technology platform combines direct visualization of protein receptor binding interactions with advanced simulation of molecular motion and signal transduction. Site 1 is considered to be the orthosteric or primary binding site for receptor activation. Site 2 is on the surface of the receptor, often referred to as the allosteric site and may potentially regulate receptor activation signaling. By visualizing and analyzing how different ligands bind to a particular target and specific sites and affect their conformational dynamics, we believe we are able to efficiently convert biologics and peptides into more accessible, patient-accommodating oral small molecules. In addition, we can enhance the pharmaceutical properties of our small molecules with the aim to elicit the desired function while maintaining superior pharmaceutical properties.

14

[Table of Contents](#)

Non-biased vs biased GPCR agonists



Graphic

Additionally, GPCR signaling can follow several pathways and molecules can be designed such that their pharmacology is selected to create “biased signaling” as illustrated above. GPCRs are known to signal not only through G-proteins, but also through β -arrestins, intracellular proteins that “arrest” the signal and stop the receptor from becoming over-stimulated through a receptor internalization mechanism. Using the three-dimensional structures of GPCRs and selection methods, we can potentially design highly selective “biased”

15

[Table of Contents](#)

molecules that preferentially activate G-protein and not β -arrestin pathways, which could lead to enhanced clinical activity as well as an improved safety profile due to lower dosage requirements.

GPCR Experience

Robust and Integrated Medicinal Chemistry to Generate and Optimize Hits on GPCR Targets

We have extensive medicinal chemistry know-how on the discovery and development of novel molecules that target GPCRs. When coupled with our deep understanding of GPCR biology, we have the potential to design appropriate chemotypes for each GPCR function as illustrated below.

15

[Table of Contents](#)

Family members with determined structures are

highlighted within the tree, and their binding pockets with the ligand



Graphic

Four character code at end of each image is Protein Data Bank ID.

Further optimization of compounds powered by our excellence in medicinal chemistry lead us to identify potent and selective oral small molecule product candidates.

Partnership with Schrödinger Leveraging its Cutting-Edge Computational Chemistry Capability

We have a collaboration collaborations with Schrödinger on the iteration and optimization of GPCR lead compounds using various next-generation physics-based computational technologies. Schrödinger is a scientific leader in chemical simulation, accurate physics-based methods, which includes among many technologies, Free Energy Perturbation ("FEP") and in silico drug discovery. Its computational platforms integrate predictive physics-based methods with machine learning to evaluate billions of compounds *in silico*, achieving experimental accuracy on properties such as binding affinity and solubility. Through this iterative process, we can accelerate evaluation and optimization of molecules *in silico* ahead of synthesis and assay, and then further optimize them through additional cycles of computation analysis.

16

[Table of Contents](#)

Structure Therapeutics integrated platform Integrated Platform



Graphic

As shown above, our collaboration collaborations with Schrödinger in our computational and chemistry module enables us to accelerate our lead optimization drug discovery process and reduce development costs. In our partnership with Schrödinger on GPCR drug discovery, we

retain the full product rights on the compounds under development.

Safety Assays

We have proactively used cell and animal-based safety assays to better screen out unwanted side effects, such as liver, cardiovascular and central nervous system toxicity at the initial stages of lead optimization, and we have designed molecules to help minimize safety risks at every step. Our in-depth understanding of GPCR signaling pathway provide us insights to design biased molecules when necessary to mitigate any unwanted liabilities while maintaining the desired activities.

Other Proprietary In-House Development Tools for Drug Synthesis and Screening

Basecamp Bio focuses specifically on technology development and early discovery and continues to innovate new methods, particularly in hit discovery.

17

[Table of Contents](#)

Basecamp Bio early discovery



Graphic

In addition to our robust iterative structure-based drug discovery platform shown above, Basecamp Bio is optimizing proprietary in-house drug discovery tools including DNA-Encoded Library technology and Affinity Mass Spectrometry technology to enable the synthesis and screening of vast numbers of small molecule product candidates at a scale that is not possible to achieve by traditional methods.

Our Lead GPCR Programs

By leveraging our unique platform capabilities, we are building a pipeline of oral small molecule product candidates designed to have patient impact and broad commercial opportunity in therapeutic areas traditionally dominated by biologics and peptide medicines. We are initially focusing on chronic metabolic, cardiovascular, and pulmonary diseases with unmet medical need.

Our GLP-1R Focused Franchise for Metabolic Disorders

To unlock the full potential of our drug discovery platform across a broad range of metabolic indications, we intend to build out our franchise approach for GLP-1R. Our franchise approach involves developing next generation GLP-1R candidates, with each exhibiting customized properties to achieve additional benefit. Our lead GLP-1R product candidate, GSBP-1290, has the potential to be a differentiated treatment for T2DM and obesity based on preclinical data.

GSBR-1290 is an oral and biased agonist of the GLP-1R, a validated GPCR drug target involved in a variety of metabolic conditions. We completed a Phase 1 SAD study for GSBR-1290 in healthy volunteers in September 2022. We initiated the Phase 1b MAD study in January 2023 and completed dosing in otherwise healthy overweight subjects in March 2023. We plan to submit In May 2023, we submitted a protocol amendment to the FDA to transition to a and initiated dosing of the Phase 2a proof-of-concept study in T2DM and obesity. We reported topline data for the 28-day Phase 1b MAD study in September 2023, in which GSBR-1290 was generally well-tolerated with no adverse event-related discontinuations and demonstrated an encouraging safety profile and significant weight loss of up to 4.9% placebo-adjusted, supporting once-daily dosing. In December 2023, we reported clinically meaningful topline data from our Phase 2a T2DM cohort, interim results from our Phase 2a obesity cohort and topline data from our Japanese ethno-bridging study of GSBR-1290. These data demonstrated

18

[Table of Contents](#)

that GSBR-1290 was generally well-tolerated, with no treatment-related SAEs over 12 weeks, with only one participant discontinuing the study due to adverse events in the T2DM cohort and none in the obesity cohort. GSBR-1290 also showed significant reduction in weight in the obesity cohort, and significant reductions in HbA1c and weight in the T2DM cohort. We expect to report the full 12-week Phase 2a obesity data in the latter half of the second quarter of 2024 with additional 24 participant data. We also fully enrolled a formulation bridging and titration optimization study to evaluate capsule versus tablet PK and explore different titration regimens of GSBR-1290. This study is expected initiation to be completed in the latter half of the second quarter of 2024, in preparation for the global Phase 2b study for obesity which we expect to initiate in the fourth quarter of 2024. A Phase 2 study in T2DM is also planned for the second half of 2023, 2024. Based on our preclinical and clinical data, we believe that GSBR-1290 and our next-generation product candidates have the potential to have highly differentiated profiles versus currently approved therapies and those in development.

18

[Table of Contents](#)

Diabetes Disease Background

Diabetes mellitus ("DM") is an endocrine related disorder of glucose regulation with subsequent hyperglycemia, or high blood sugar, which develops following pancreatic β -cell destruction or dysfunction resulting in severe loss of insulin production, also known as type 1 diabetes, or β -cell dysfunction and loss of insulin sensitivity, also known as T2DM. T2DM is more common in adults and accounts for around 90% of all diabetes cases. In T2DM, the loss of insulin sensitivity is often preceded by being overweight or obese, and manifests along with hypertension and dyslipidemia. Regardless of etiology, once hyperglycemia develops, patients with diabetes share a common disease course characterized by atherosclerotic diseases such as coronary heart disease, stroke, peripheral vascular disease and/or, microvascular diseases such as nephropathy, retinopathy, and neuropathy. Additionally, hyperglycemia is associated with metabolic dysfunction, chronic inflammation, and an increase in infections.

According to the 2021 International Diabetes Federation Diabetes Atlas, more than one in ten adults are now living with diabetes globally. The estimated prevalence of diabetes in adults aged 20 to 79 years has more than tripled since 2000, from an estimated 151 million (4.6% of the global population in this age group at the time) to 537 million (10.5%) today. If trends continue, the number will jump to a staggering 783 million (12.2%) by 2045. The number of adults with diabetes in the United States reached 32.2 million in 2021, while China has the largest numbers of adults with diabetes at 140.9 million. In 2021, approximately 6.7 million adults aged 20 to 79 are estimated to have died as a result of diabetes or its complications. According to American Diabetes Association ("ADA"), the total estimated cost of diagnosed diabetes in the United States increased to \$327 billion in 2017, which included \$237 billion in direct medical costs and \$90 billion in reduced productivity.

In newly diagnosed T2DM patients, treatment is focused on improving modifiable risk factors such as obesity, low physical activity and high caloric diet through patient education that includes instruction on maintaining a healthy lifestyle including nutritional counseling, avoiding

excessive calories and rapidly absorbed carbohydrates, and physical exercise. Patients who are unable to achieve glycemic control through weight loss and/or lifestyle modifications should be started on single or combination glucose-lowering medications to lower their glycemic burden and reduce the risk of cardiovascular and other complications.

Obesity Disease Background

Obesity, defined as a body mass index ("BMI") of ≥ 30 kg/m², is a major independent risk factor for T2DM. Approximately 90% of T2DM patients are considered either overweight with a BMI between 25.0 kg/m² and 29.9 kg/m², or obese with a BMI of 30 kg/m² or greater. Worldwide obesity has nearly tripled between 1975 and 2016. As of 2020, 1.9 billion (39%) adults were overweight, including over 764 million (15%) adults who were obese. In men, being slightly overweight increased diabetes risk seven-fold and in women, being slightly overweight increased diabetes risk twelve-fold. Being obese increased the risk to 60-fold.

Obesity affects nearly one third of all adults in the United States and is associated with a range of comorbidities, such as T2DM, cardiovascular disease, obstructive sleep apnea, and cancer. Importantly, even

19

[Table of Contents](#)

modest weight reduction, on the order of five to ten percent, can significantly reduce comorbidities and improve health-related outcomes and has been recently recommended by the major scientific societies (European Association of the Study of Diabetes ("EASD") and ADA). Obesity therefore represents an immense commercial opportunity with very few approved therapies on the market. The GLP-1R agonist semaglutide, approved for use in T2DM, has also been approved for weight management for which it is marketed under the brand name Wegovy, which is estimated to reach peak sales of \$6.7 billion in 2026.

Relationship Between T2DM and Obesity

T2DM and obesity are not independent conditions, as the majority of patients with T2DM are obese. Observed increases in the prevalence of T2DM are related to the increasing prevalence of obesity and multiple mechanisms have been proposed through which they may be linked pathophysiologically. Upper

19

[Table of Contents](#)

body and visceral fat are associated with T2DM, metabolic syndrome and cardiovascular disease. Obesity is a major contributor to poor metabolic control in patients with T2DM.

Increasingly, weight reduction is seen as an important goal of therapy for patients with T2DM. Weight loss in the first year of treatment of T2DM has been associated with an increase in life expectancy. According to the ADA Standards of Medical Care in Diabetes—2022, management of obesity is an important factor in the treatment of diabetes since even a small degree of weight loss can improve control of blood sugar levels, resulting in a decreased need for glucose-lowering medications. Given this information, a therapy that can both lower blood glucose and help with weight management in T2DM could have near-term benefits in glycemic control and longer-term benefits in increased insulin sensitivity and reduction of cardiovascular risk.

Current Treatments for T2DM and Obesity

First-line treatment for patients with T2DM involves lifestyle modifications and metformin. If glycemic control remains inadequate, an additional oral glucose lowering medication should be added. Options include sodium-glucose transport protein 2 inhibitors, dipeptidyl peptidase-4

inhibitors, and GLP-1R agonists. Current treatment algorithms suggest that GLP-1R agonists should be preferentially used after metformin failure in patients who are at high risk for, or who have established, atherosclerotic cardiovascular disease. Several scientific societies, including the EASD and ADA, recommend GLP-1R agonists as first line therapy in patients with established atherosclerotic cardiovascular disease or in those at high risk of developing disease. According to Global Data, Eli Lilly and Company ("Eli Lilly"), Novo Nordisk, Merck and Sanofi S.A. ("Sanofi"), have captured significant market share in the approximately \$46.6 \$65.4 billion market for glucose-lowering agents in 2021, 2023, which is projected to grow to \$60.5 \$115.4 billion by 2027 as depicted below.

20

[Table of Contents](#)

Historical and projected global obesity and type-2 diabetes drug sales by class



Graphic

Overview of GLP-1R Signaling Pathway and Target Biology

GLP-1 is an incretin peptide secreted in the intestinal tract in response to food intake. GLP-1 stimulates insulin secretion from pancreatic β -cells and inhibits glucagon secretion from pancreatic α -cells. GLP-1 receptors are located on various cell and tissue types including pancreatic β -cells, central and peripheral neurons, cells of the intestinal tract, vascular smooth muscle and endothelial cells, coronary arteries, and the sino-atrial node of the heart. Through actions at these receptors, GLP-1 and GLP-1R agonists have demonstrated widespread therapeutic effects in patients with diabetes, including stimulating insulin secretion and lowering blood glucose levels, slowing gastric emptying, reducing caloric intake, promoting weight loss, improving lipoprotein metabolism, lowering systolic blood pressure, improving complications from atherosclerotic cardiovascular diseases, and reducing cardiovascular disease morbidity and mortality, as illustrated below.

20 21

[Table of Contents](#)

GLP-1R pathway and target biology



Graphic

Endogenous GLP-1 is rapidly degraded *in vivo* by DPP-4, with a half-life of one to two minutes. The development of GLP-1R agonists for the treatment of diabetes and obesity has involved modifications to the GLP-1 peptide and/or conjugation to carrier compounds or matrices that delay degradation after subcutaneous administration.

The **five six** marketed GLP-1R and GLP-1R/GIPR agonists are synthetic peptides and include liraglutide and semaglutide marketed by Novo Nordisk; dulaglutide and tirzepatide marketed by Eli Lilly; exenatide marketed primarily by AstraZeneca plc ("AstraZeneca"); and lixisenatide marketed by Sanofi. According to Global Data, these **five six** GLP-1R and GLP-1R/GIPR peptides approved for T2DM and/or obesity collectively generated approximately **\$13.2 \$65.4** billion in worldwide sales in **2020, 2023**, which is projected to reach **\$36.4 \$115** billion by **2026, 2027**.

Rybelsus is an oral formulation of semaglutide co-formulated with sodium N-8-(2-hydroxybenzoyl) amino caprylate to limit degradation and improve oral absorption. To date, there are no approved oral small molecule therapies targeting this pathway.

Common side effects of GLP-1R and GLP-1R/GIPR agonists include nausea, vomiting, and diarrhea, which are most pronounced when starting therapy or increasing the dose. Generally, these effects correlate with times of maximum drug concentrations and ameliorate with continued therapy. Typically, slow up-titration to the desired dose can mitigate these side effects. However, once-weekly injectable GLP-1R and GLP-1R/GIPR agonists typically require a long titration period to achieve an optimal dose, potentially delaying therapeutic benefit. Once-daily therapy with an oral small molecule may provide flexibility in titration and allow a combined approach with other oral therapies.

The Unmet Medical Need for Improved GLP-1R Therapeutics in Diabetes and Obesity

GLP-1R agonists provide multiple beneficial effects in patients with T2DM, including excellent glycemic control with low risk of hypoglycemia, weight loss and protection against cardiovascular and renal complications. However, we believe approved GLP-1R agonists have shortcomings in terms of patient convenience, ease of dosing, and cost.

Injectable peptide GLP-1R agonist peptides require patients to self-inject, require inconvenient refrigerated storage and are costly. In addition, long acting GLP-1R agonists typically require long titration periods to

21 22

[Table of Contents](#)

reach an optimal dose for disease management in order to avoid treatment-associated gastrointestinal side effects.

Oral semaglutide (Rybelsus), the first approved oral GLP-1R peptide agonist, provides an option for patients who are unable or unwilling to self-administer. However, Rybelsus requires a stringent dosing protocol and dosing with up to four ounces of water with no food or beverage within 30 minutes. Additionally, the product's absorption enhancer may affect the absorption of other concomitantly administered oral medications.

We believe there is an unmet medical need for orally administered GLP-1R agonists that meet or exceed efficacy and safety parameters of available drugs with less stringent preparation requirements. Such existing constraints include restrictive food or fluid dosing protocols, refrigeration, maintenance of effective concentrations throughout the dosing interval, without interfering with the absorption of concomitant medications and that offer the potential for combination products with other glucose lowering agents or other commonly co-administered therapies.

In addition to glycemic control, weight management is increasingly viewed as important to the management of T2DM. Injectable GLP-1R agonists, liraglutide and semaglutide result in weight loss at doses approved for treatment of T2DM, while higher doses of each drug, indicated for chronic weight management, result in greater weight loss. At an appropriate dose, an oral GLP-1R agonist may play a role in managing both blood glucose and weight.

Our Solution: Small Molecule GLP-1R Agonist

GLP-1, along with GIPR, comprise the incretin family, peptide hormones secreted into the blood by enteroendocrine cells in the gut, which play a role in glycemic control. We are taking a franchise approach to our GLP-1R programs by developing next generation GLP-1 agonists and potential GIPR modulators. Leveraging the depth of our GLP-1R/GIPR structure platform, proprietary compound library and deep biology and disease insights, we are advancing multiple generations of structurally distinct GLP-1R agonist molecules through lead optimization. Each molecule is designed to have a different tissue penetration profile and other incretin activities in order to maximize the value and/or realize the full potential offered by our in-house platform.

GSBR-1290 Selective GLP-1R Agonist Program

We are developing GSBR-1290, a biased orally-available small molecule GLP-1R agonist, initially as a treatment for T2DM and obesity. Due to its significant preclinical activity and oral availability, we believe that GSBR-1290 has the potential to be a differentiated treatment with no restrictions on diet or concomitant therapies.

22 23

[Table of Contents](#)

GSBR-1290 analog bound GLP-1R cryo-EM structure



Graphic

GSBR-1290 was designed through our internal structure-based drug discovery platform. As shown above, multiple small molecules bound to GLP-1R structures have been generated to guide iterative chemistry design efforts. GSBR-1290 is also designed to be a biased GPCR agonist, which only activates the G-protein pathway without β -arrestin signaling at therapeutic doses, thereby avoiding receptor internalization and de-sensitization. In an intravenous glucose tolerance test ("ivGTT") in NHPs, GSBR-1290 increased glucose-dependent insulin secretion to

a similar level achieved by liraglutide, an approved injectable GLP-1R agonist. In a repeat food intake study in NHPs, GSBR-1290 showed a significant decrease in body weight relative to the placebo and surpassed that seen with liraglutide.

GSBR-1290 Preclinical Data, Pharmacology, and Biomarker Data

In NHP ivGTT studies, glucose was injected five minutes following intravenous administration of either GSBR-1290 (0.05 mg/kg) or liraglutide (0.1 mg/kg). Plasma samples were taken at indicated timepoints to evaluate insulin and glucose levels. GSBR-1290 demonstrated statistically significant decreases in blood glucose concentration via stimulation of insulin secretion in a glucose-dependent manner, similar to liraglutide which was dosed at an equivalent approved human dose.

Robust activity in non-human primate acute ivGTT studies



Graphic

23 24

[Table of Contents](#)

Data were presented as mean ± standard error of the mean ("SEM"); one-way ANOVA followed by Dunnett's multiple comparisons test.
p<0.05, **p<0.01, *p<0.001 vs vehicle*

As shown below, in a seven day repeat oral dosing study in NHPs, GSBR-1290 was evaluated at once-daily oral doses of 2 mg/kg, 6 mg/kg, and 10 mg/kg and compared to placebo and liraglutide. Food intake was measured each day over the first six days of the study and reported as an average of these measurements. ivGTT and body weight were performed before dosing and on the sixth day (body weight) or seventh day (ivGTT) of post-dosing. At all doses of GSBR-1290, glucose reduction was shown to be statistically significantly different versus vehicle and comparable to liraglutide. Similarly, all doses increased insulin secretion significantly except at 6 mg/kg dose, which only achieved statistical p value at 0.055 due to a slightly greater data variability. At 6 mg/kg and 10 mg/kg, a statistically significant reduction of average food intake measured over the first six days of the study compared to vehicle was observed. At 10 mg/kg of GSBR-1290, the average food intake from Day 1 to Day 6 was only 59% relative to liraglutide group. GSBR-1290 at 6 mg/kg and 10 mg/kg also showed a significant decrease in body weight relative to placebo and surpassed liraglutide, with the highest dose of GSBR-1290 achieving more than eight percent reduction in average body weight versus baseline in one week.

Seven day repeat oral dosing study in non-human primates



Graphic

Data were presented as mean ± SEM; one-way ANOVA followed by Dunnett's multiple comparisons test.
p<0.05, **p<0.01, *p<0.001 vs vehicle*

In the description of our clinical trials and preclinical studies below and elsewhere in this Annual Report, n represents the number of participants in a particular group and p or p-values represent the probability that random chance caused the result (e.g., a p-value of 0.01 means that there is a 0.1% probability that the difference between the placebo group and the treatment group is purely due to random chance). A p-value of less than or equal to 0.05 is a commonly used criterion for statistical significance, and may be supportive of a finding of efficacy by regulatory authorities.

GSBR-1290 was demonstrated to be generally well tolerated based on its 28-day GLP toxicology studies with no-observed-adverse-effect level ("NOAEL") dose at 1000 mg/kg/day in rats. The estimated therapeutic window is more than 1000-fold based in rats based on its 28-day GLP toxicology studies.

In addition, we conducted a preclinical comparison study of GSBR-1290 and PF-06882961, a clinical stage compound in development by Pfizer. Unlike GSBR-1290, PF-06882961 is a partially biased GLP-1R agonist, which could lead to de-sensitization of the receptor *in vivo*. In an experiment conducted in-house, GSBR-1290 demonstrated comparable *in vivo* activity to PF-06882961 at a lower exposure. In the acute ivGTT studies, GSBR-1290 achieved similar activity to liraglutide at average concentration around 34 nanomolar ("nM") (0.05 mg intravenous), comparing to a similar activity achieved by PF-06882961 in an in-house experiment at an

24

[Table of Contents](#)

average concentration around 442 nM (0.3 mg intravenous). This suggests that the concentration needed to achieve full activity for GSBR-1290 is at a level much lower than that for PF-06882961. PF-06882961 has been studied in SAD and MAD studies with a maximum dose of 200 mg/BID to achieve maximum HbA1c activity and weight management.

25

[Table of Contents](#)

In-house data showed that PF-06882961 was positive in a glutathione trapping assay. GSBR-1290 was inactive in this assay, suggesting reduced risks with long-term use. In addition, GSBR-1290 also did not show activity as a time dependent inhibitor ("TDI") for cytochrome P450 3A4 or CYP3A4. ("CYP3A4"). PF-06882961 was reported as a CYP3A4 TDI, which, if confirmed in clinical trials, suggests the potential for interactions with the 30–50% of marketed drugs metabolized through this pathway.

GSBR-1290 Phase 1 Healthy Volunteer Trial

In September 2022, we completed a first-in-human Phase 1 SAD study for GSBR-1290 in 48 healthy adult volunteers between the ages of 18 and 55. The objective was to assess drug safety, tolerability and PK. The study enrolled six cohorts of eight participants assigned to receive a single dose of GSBR-1290 or placebo in a 3:1 ratio. Doses ranged from 1 mg to 90 mg across the six cohorts. The fourth cohort received 15 mg administered either under a fed condition, which consisted of a standardized high fat breakfast, and under a fasted condition, in each case to characterize the effect of food on the PK of GSBR-1290. A schema of our Phase 1 SAD study is presented below:

Schema of our GSBR-1290 Phase 1 SAD study in healthy volunteers



Graphic

GSBR-1290 Phase 1 PK and PD Data in Healthy Volunteers

In the study, PK parameters of systemic exposure, C_{max} and AUC, increased with doses of GSBR-1290 across the dose range from 1 mg to 90 mg GSBR-1290. GSBR-1290 exhibited supra dose proportionality from 1 mg to 30 mg followed by less than dose-proportional from 30 mg to 90 mg.

The 30mg dose AUC provided more than double the effective AUC_{0-24h} required for glycemic control, derived from non-human primate PK/PD data. Food intake (high fat meal) was associated with a ~36%

25

[Table of Contents](#)

decrease in the geometric mean C_{max} but no significant change in mean AUC value, with 80% relative bioavailability, based on AUC compared with the fasted state.



Graphic

26

[Table of Contents](#)

GSBR-1290 Phase 1 Safety Data in Healthy Volunteers

GSBR-1290 was shown to be generally well tolerated at all dose levels administrated in this Phase 1 SAD study.

No SAEs and no adverse changes in laboratory tests (including hematology, chemistry and coagulation) were observed. No trial stopping criteria were met. Adverse events ("AEs") did not result in any early terminations or subject discontinuations from participation in this study.

Treatment-emergent AEs ("TEAEs") were reported for 32 of 36 participants (89%) following fasted administration of GSBR-1290 and for 7 of 12 participants (58%) following administration of placebo, with a total of 109 TEAEs.

Following administration of GSB-1290 in the fasted state, most TEAEs were classified as mild (69 of 109, or 63% of all TEAEs) in severity, with 34 TEAEs (31% of all TEAEs) classified as moderate in severity. Six TEAEs (6%) were classified as severe, including four events of vomiting, one event of nausea and one event of catheter site infection. There was an apparent dose-related trend in the severity of TEAEs following single doses of GSB-1290, with severe TEAEs reported following the 60 mg and 90 mg doses of GSB-1290, but not following low doses (1 mg, 10 mg, 15 mg). Occurrences in TEAEs of moderate intensity were also higher following higher dose range of GSB-1290.

The following table shows an overall summary of TEAEs that were reported in the study.



Graphic

[Table of Contents](#)

Low dose GSB-1290 includes 1 mg, 10 mg and 15 mg fasted and high dose GSB-1290 includes 30 mg, 60 mg and 90 mg fasted.

If a participant had multiple occurrences of a TEAE, the participant was presented only once in the Participant count for a given Preferred Term. Occurrences were counted each time.

There was no notable difference in the overall incidence or severity of treatment-related AEs under fasted and fed administration of GSB-1290 at a dose level of 15 mg. There was a higher incidence of related TEAEs of vomiting and headache following fasted administration (three of six participants, or 50%) compared to fed administration (one of six participants, or 17%).

The most common TEAEs reported in at least four of 36 participants (>10%) who received GSB-1290 were nausea, headache, vomiting, dehydration, decreased appetite, dizziness, and diarrhea.

Across the various dose levels, there were apparent dose-related trends in the overall incidence of common TEAEs. The incidence of the TEAEs described above was notably higher following fasted administration of the high dose GSB-1290 treatments (30 mg, 60 mg, 90 mg) than the low dose GSB-1290 treatments (1

[Table of Contents](#)

mg, 10 mg, 15 mg) and placebo, with a similar observation in treatment-related AEs of nausea, vomiting, dehydration, and headache of at least moderate severity.

We believe all TEAEs observed during the study are in line with the proposed treatment mechanism and typically derive from impacts on appetite, nausea, and vomiting. There was an apparent increasing trend in heart rate over time in both low (1 mg, 10 mg, 15 mg) and high dose (30 mg, 60 mg, 90 mg) GSB-1290 groups. This increase appeared to peak at 12 hours post-dose and was notably larger in the high dose GSB-1290 groups. Increases in heart rate over time were observed in the pooled placebo group but to a much lesser extent.

In summary, GSB-1290 was shown to be generally well tolerated when administered as a single dose of up to 90 mg. However, there were dose-related trends in the incidence, severity and causality of TEAEs, particularly GI related TEAEs, consistent with what has been previously reported in clinical trials involving the GLP-1RA class of drugs. There were no treatment-related AEs reported in patients who received placebo.

PK parameters of systemic exposure increased with dose of GSB-1290 across the dose range from 1 mg to 90 mg GSB-1290.

GSB-1290 Non-clinical Safety Pharmacology and Toxicology Studies

A standard battery of nonclinical safety pharmacology studies (central nervous system, cardiovascular and respiratory) has been completed with GSB-1290 with no findings anticipated to be of clinical relevance. Genotoxicity assessments demonstrated an absence of genotoxicity potential.

In the 4-week and 13-week GLP toxicology study in rats, the **NOAEL** no-observed-adverse-effect level ("NOAEL") dose was considered to be 1000 mg/kg/day, the highest dose tested. In the 4-week and 13-week GLP toxicology study in NHPs, GSB-1290 showed pharmacologically related events such as inappetence and bodyweight loss, which were reversible with sufficient recovery periods. There were no GSB-1290-related deaths during the course of study and no GSB-1290-related changes in organ weights, gross and histopathology examinations at the end of the dosing and recovery periods. In the 13-week study, NHPs of both sexes in all dose groups, including in the control group, had minimal to moderate multifocal necrosis/infiltration in the liver. The root cause of these liver abnormalities was not determined, but these findings were considered unrelated to GSB-1290. The FDA reviewed our 13-week GLP toxicology studies in rats and NHPs and agreed that these liver abnormalities were not considered a new non-clinical safety signal related to GSB-1290.

In nonclinical animal models, GSB-1290 demonstrated statistically significant decreases in blood glucose concentration and increases of insulin secretion.

27

Table of Contents

In a recent 6-month GLP toxicology study in rats, GSB-1290 demonstrated a NOAEL dose at 1000 mg/kg/day, which supports an estimated more than 100 fold safety window up to 120 mg human dose. We have initiated also conducted a 9-month non-human primate (NHP) GLP toxicology study and found no test article-related change in heart rates or QTc intervals. No meaningful increases in the 26-week chronic liver enzymes, ALT/AST, were observed in either the rat or NHP study. There were no significant findings in embryo-fetal developmental toxicology studies in rats and 39-week studies in NHP and embryo-fetal development studies that we believe will be required by regulatory agencies to continue dosing beyond 13 weeks in Phase 2b. rabbits.

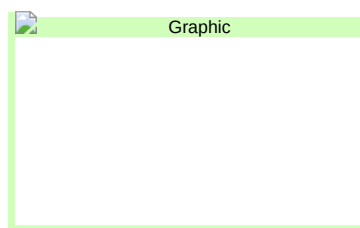
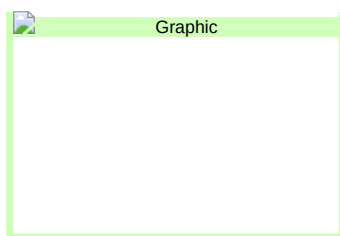
GSB-1290 Phase 1b MAD study

We submitted an IND to the FDA to support initiation of a GSB-1290 The Phase 1b MAD study focused on the safety and received FDA allowance tolerability of GSB-1290 in September 2022. After initiation in January 2023, we enrolled 24 healthy overweight or obese subjects between individuals. Participants were randomized 3:1 to GSB-1290 or placebo across three dose cohorts with target doses of 30mg, 60mg or 90mg.

GSB-1290 demonstrated reductions in mean body weight ranging up to 4.9 kg compared to baseline, and up to 4.9% placebo-adjusted.

28

Table of Contents



Percent Weight Change from Baseline to Day 28

	Placebo (n=5)	GSBR-1290 30 mg (n=6)	GSBR-1290 60 mg (n=6)	GSBR-1290 90 mg (n=5)
% weight change from baseline	-0.5%	-1.6%	-5.2%	-5.4%
% weight change placebo-adjusted (90% CI)	—	-1.1% (-3.8 to 1.7)	-4.6% (-6.6 to -2.7)	-4.9% (-7.8 to -1.9)
Exploratory p-value vs. placebo	—	0.494	0.002	0.013

GSBR-1290 demonstrated an encouraging safety and tolerability profile following once-daily dosing. No participants discontinued the study drug due to adverse events. The majority of 18 adverse events reported were mild, with no severe or serious adverse events observed. As expected for this class, leading adverse events were gastrointestinal-related, with the two most common gastrointestinal adverse events being nausea and 55. diarrhea, with higher incidences observed in all three cohorts compared to placebo. There were no clinically meaningful changes in liver function tests.

Summary of Treatment Emergent Adverse Events

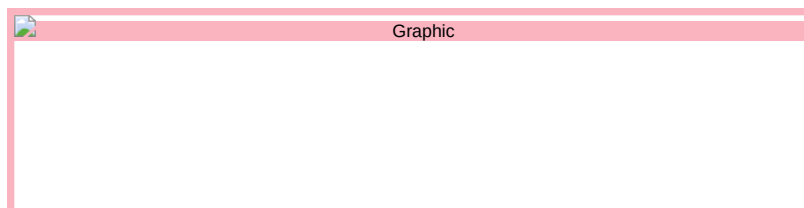
	GSBR-1290 30 mg (n=6)	GSBR-1290 60 mg (n=6)	GSBR-1290 90 mg (n=6)	Placebo pooled (n=6)
Event, N (%)				
Any TEAE	5 (83)	6 (100)	6 (100)	4 (67)
Any TEAE by maximum severity				
Mild	4 (67)	4 (67)	3 (50)	4 (67)
Moderate	1 (17)	2 (33)	3 (50)	0
Severe	0	0	0	0
Any Serious Adverse Events	0	0	0	0

GSBR-1290 Phase 2a study in diabetes and obesity

The randomized, double-blind, 12-week placebo-controlled Phase 2a clinical trial has enrolled a total of 94 participants to date, including 60 participants randomized to GSBR-1290. The T2DM cohort enrolled 54 participants, randomized to GSBR-1290 at 45 mg (n=10) or 90 mg (n=26), or placebo (n=18), dosed once daily. The obesity cohort initially enrolled 40 participants randomized to GSBR-1290 at 120 mg (n=24) or placebo (n=16), dosed once-daily. An additional 24 participants have been enrolled in the obesity arm as previously announced in September 2023 to replace those for whom 12-week weight data was not collected as a result of a data collection omission. These replacement participants have also been randomized 3:2 to GSBR-1290 or placebo.

The primary objective is to assess drug safety and tolerability. The secondary objectives are to evaluate PK and PD and determine endpoints of the starting dose for titration and help define the titration scheme including the dose level and duration of steps. The study enrolled three cohorts of eight participants who received multiple ascending doses of GSB-1290 or placebo in a 6:2 ratio. We completed dosing of Cohorts 1 through 3 in March 2023. Cohort 1 doses started at 5 mg daily and escalated up to 60 mg weekly over four weeks. Cohort 2 doses started at 10 mg and escalated up to 90 mg daily over four weeks. Cohort 3 doses started at 10 mg for two weeks and escalated to 30 mg for an additional two weeks. A schema of our Phase 1b MAD study is presented below.

Schema of our GSB-1290 Phase 1b MAD study in healthy overweight/obese subjects



Phase 2a proof-of-concept study

We plan to submit a protocol amendment to initiate a Phase 2a proof-of-concept portion of the study in T2DM and healthy overweight or obese subjects and expect to report initial data in the second half of 2023. The primary objective is to assess safety and tolerability of GSB-1290. Key secondary endpoints include reduction in healthy obese subjects weight for both obesity and T2DM subjects. Secondary objectives include assessing changes in body weight, HbA1c and other PD measures in T2DM subjects cohorts, as well as reduction in HbA1c for the T2DM cohort.

GSB-1290 Safety and tolerability results

GSB-1290 demonstrated an encouraging safety and tolerability profile following repeated, daily dosing for all doses studied (up to 120 mg) in the obesity and T2DM cohorts, with results summarized as follows:

- The majority (88 to 96%, depending on study arm) of AEs reported were mild to moderate.
- There were no SAEs related to study drug.
- As expected for this mechanism of action, leading AEs were gastrointestinal-related. The two most common AEs were nausea and vomiting.
- There were no cases of elevated liver enzymes in the obesity cohort. One participant in the T2DM treatment group experienced an event of elevated liver enzymes without an increase in bilirubin initially at day 8 while receiving 5 mg of study drug. This participant was diagnosed with fatty liver disease while in the study.
- Of the 60 participants dosed with GSB-1290, only one participant discontinued the study due to AEs related to study drug (none in the obesity cohort and one (2.8%) in the T2DM cohort).

Summary of Treatment Emergent Adverse Events (TEAEs)

Event, N (%)	Phase 2a T2DM Cohort			Phase 2a Obesity Cohort	
	(12-week data)			(12-week interim data)	
	GSB-1290 45 mg (n=10)	GSB-1290 90 mg (n=26)	Placebo (n=18)	GSB-1290 120 mg (n=24)	Placebo (n=16)
Any TEAE	10 (100)	25 (96.2)	8 (44.4)	23 (95.8)	11 (68.8)
Any TEAE by maximum severity					
Mild	2 (20)	6 (23.1)	6 (33.3)	6 (25)	9 (56.3)
Moderate	7 (70)	17 (65.4)	2 (11.1)	17 (70.8)	2 (12.5)
Severe	0	2 (7.7)	0	0	0
Any SAEs	1 (10)	1 (3.8)	0	0	0
Any SAEs related to study drug	0	0	0	0	0

GSB-1290 Efficacy results

GSB-1290 demonstrated clinically meaningful activity in both T2DM and obesity cohorts, with results summarized as follows:

- In the T2DM cohort, there was a statistically significant HbA1c reduction (-1.01 to -1.02%, placebo-adjusted) at Week 12 (Table 1). The study demonstrated a statistically significant and clinically meaningful reduction in weight at Week 12 (-3.26% to -3.51%, placebo-adjusted) (Table 2). Weight loss continued to decrease through Week 12.
- Results of the interim analysis in the obesity cohort showed a statistically significant and clinically meaningful decrease in weight at Week 8 (-4.74%, placebo-adjusted) (Table 3). Weight loss continued to decrease throughout the eight weeks of treatment.

Table 1: Diabetes cohort least square means difference (LSM) change in HbA1c from baseline to 12 weeks (%)

30

Table of Contents

	GSBR-1290		GSBR-1290
	45 mg	90 mg	Placebo
	(n=10)	(n=26)	(n=18)
LSM HbA1c change from baseline (%)	-0.79	-0.84	0.18
% HbA1c change placebo-adjusted (LSM, 95% confidence interval (CI))	-1.01	-1.02	
	(-1.73, -0.29)	(-1.59, -0.44)	
P-value vs. placebo	p= 0.008	p= 0.001	

LSM, CI and p-value from Mixed Model for Repeated Measures

Table 2: Diabetes cohort LSM change in weight from baseline (%)

	GSBR-1290		GSBR-1290
	45 mg	90 mg	Placebo
	(n=10)	(n=26)	(n=18)
LSM weight change from baseline (%)	-3.32	-3.22	0.04
% weight change placebo-adjusted (LSM, 95% CI)	-3.51	-3.26	—
	(-5.58, -1.43)	(-5.17, -1.36)	
P-value vs. placebo	p= 0.0019	p= 0.0013	—

LSM, CI and p-value from Mixed Model for Repeated Measures

Table 3: Obesity Cohort LSM change in weight from baseline (%) 8 week interim results

	GSBR-1290	
	120 mg	Placebo
	(n=24)	(n=16)
LSM weight change from baseline (%)	-5.5	-0.82
% weight change placebo-adjusted (LSM, 90% CI)	-4.74	
	(-6.74, -3.10)	
P-value vs. placebo	p< 0.0001	

GSBR-1290 Phase 1 Japanese Bridging Study

The 4-week Phase 1 Japanese ethnobridging study included healthy lean Japanese participants randomized to GSBR-1290 (n=9) and placebo (n=3), and healthy lean non-Japanese participants receiving GSBR-1290 (n=6). GSBR-1290 demonstrated a substantial weight reduction in

Japanese participants (-3.91% on GSB-1290 vs -1.67% placebo) and in non-Japanese participants (-5.13% not placebo-adjusted), with no discontinuations or dose reductions, and no SAEs. These data will be used for regulatory interactions in Japan in preparation for potential future global studies of GSB-1290.

GSB-1290 Six- and Nine-Month Toxicology Studies

In preparation for Phase 2b development with longer durations of treatment, we have completed six-month (rodent) and nine-month (non-human primate) toxicology studies to evaluate the safety of GSB-1290. No major findings were observed in either study, with no test article-related changes observed in body weight the liver, including ALT/AST, at all doses, and a more than 100 fold safety window at the 120 mg therapeutic dose.

Amylin Receptor Agonist - Combination GLP-1R Program

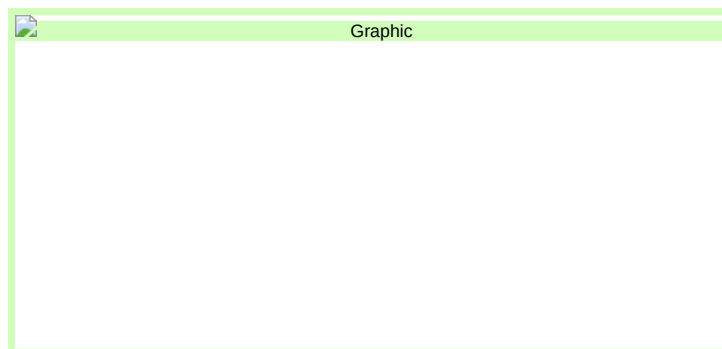
Amylin is co-secreted with insulin from β pancreatic cells upon nutrient delivery to the small intestine as a satiety signal, acts upon sub-cortical homeostatic and hedonic brain regions, slows gastric emptying, and

31

[Table of Contents](#)

suppresses post-prandial glucagon responses to meals. Therefore, new pharmacological amylin analogues can be used as potential anti-obesity medications in healthy individuals who are overweight or obese subjects. The exploratory objectives are to assess metabolite formation. obese.

The Phase 2a part of the study will enroll at least 69 subjects, which number may increase based upon the final study design. Approximately 54 T2DM subjects will be randomized in three groups to receive GSB 1290 45 mg or 90 mg or placebo. There will be a four week titration period followed by eight weeks of daily treatment at the target dose. Amylin tool compound showed add-on effects when used with semaglutide



In addition, at least 15 healthy overweight collaboration with Schrödinger, we are taking a structure-based drug discovery approach to identify oral small molecule amylin agonists for daily use either alone or obese subjects will receive GSB 1290 or placebo or, after a four week titration period, GSB 1290 90 mg daily for in combination with GLP-1R agonists to treat obesity and T2DM. We have identified two novel lead series with promising potency and PK profiles. We have obtained multiple high quality Cryo-EM structures and established in-house *in vivo* animal models, which enable us to four weeks followed by 120 mg daily for four to

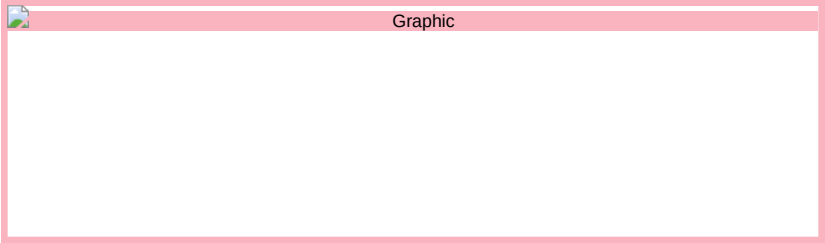
28

[Table of Contents](#)

six weeks, depending on the final study design. We may make additional modifications to the initial study design when we submit **advance** our final protocol amendment to the FDA.

We also anticipate initiating a Phase 2b study in 2024, subject to favorable results in the Phase 2a study. A schema of our Phase 2a proof-of-concept study is presented below:

Schema of our GSB-1290 Phase 2a lead optimization effort with high efficiency. In an in-house proof-of-concept study in T2DM and healthy overweight/obese subjects



Next Generation GLP-1R Program

In rats, our next generation GLP-1R program, we have identified hits for small molecule dual GLP-1R/GIPR modulation and we amylin tool compound (ACCG-0184) showed additional beneficial effects when used as an add-on treatment to a GLP-1R agonist. We are planning to select a development candidate in the second half of 2024.

GenerationGIPR Modulator - Combination GLP-1R Program

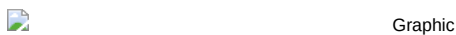
In our GIPR program, we have identified multiple GIPR agonist, dual GLP-1R/GIPR agonist and GIPR antagonist hits for small molecule GIPR modulation. We believe GLP-1R/GIPR modulation has the potential to provide a differentiated treatment in diabetes and obesity.

Recent third-party clinical data showed tirzepatide, a GLP-1R/GIPR modulator, was superior to semaglutide with respect to glycemic control. The glycated hemoglobin level target of less than 5.7% (normoglycemia) was met in 27 to 46% of the T2DM patients who received tirzepatide compared to 19% of those who received semaglutide. The body weight reduction and gastrointestinal related side effects were similar to the GLP-1R agonists. In addition, many patients who received tirzepatide were noted to have improved biomarkers of insulin sensitivity.

We have obtained both GIP and tirzepatide bound GIPR structures along with GLP-1R structures to guide our small molecular design.

[Table of Contents](#)

Multiple Structures of ligand bound GLP-1R, GIPR, GCGR



[Table of Contents](#)

As shown above, representative three-dimensional structures of the incretin GPCRs (e.g., GIPR, GLP-1R, Glucagon receptor) are available for structure-based drug discovery. This structural data enables the ability to design dual and tri modulators of this important class of metabolic GPCRs. The GIPR model shown below suggests that one of our dual GLP-1/GIPR agonists may extend to fill the pocket (highlighted in color) occupied by our GLP-1/GIPR agonist hits. Multiple approaches were applied for hit identification, including a screen of our proprietary incretin compound library. Weak antagonists and agonists were identified. After several rounds of structure activity relationship evolution, a full potential GLP-1R/GIPR antagonist and initial dual GLP-1R/GIPR agonist hit leading to the discovery of an optimized dual GLP-1R/GIPR agonist hit. While displaying different GIPR activity, both compounds still maintained certain levels of GLP-1R activities. **We are planning to select a development candidate in the first half of 2025.**

Next generation GIPR agonist/dual incretin GLP-1R/GIPR agonist agonist/antagonist hits identified for potential GLP-1R combinations



Graphic

Our LPA1R and APJR Program for the Treatment of IPF

We are developing LTSE-2578, an investigational oral small molecule LPA1R antagonist for the treatment of IPF. We believe LTSE-2578 is a differentiated molecule because it demonstrated potent in vitro and in vivo activity in preclinical IPF models and dose dependent inhibition of histamine release as the pharmacodynamic marker. **We have completed IND-enabling studies including 28 day GLP-toxicology studies in dogs and rats.**

33

[Table of Contents](#)

We are planning to initiate a first-in-human Phase 1 single and multiple ascending dose study in healthy volunteers in the second quarter of 2024.

In addition, we are developing ANPA-0073, an investigational oral small molecule APJR agonist, for the treatment of IPF. When compared to a non-biased APJR agonist (Apelin-12) in a preclinical study, ANPA-0073 avoided hypotension. In September 2022, we completed a Phase 1 SAD and MAD study evaluating ANPA-0073, in which it was generally well tolerated in healthy human volunteers. We expect to conduct additional preclinical studies **to be followed by a Phase 1 formulation bridging PK study in Australia. We also plan and are evaluating plans to initiate a Phase 2 study in 2024 in the United States. IPF.**

IPF Disease Background

IPF is a life-threatening chronic interstitial lung disease characterized by progressive fibrosis of lung tissue leading to impaired blood oxygenation, progressive deterioration in lung function, and ultimately respiratory failure. IPF occurs primarily among patients between the ages of 50 and 70 years and is associated with high mortality, with median survival time between three- and five-years following diagnosis. Estimated prevalence of IPF is 13 to 20 per 100,000 people worldwide. In the United States, approximately 100,000 people are affected, and 30,000 to 40,000 new cases are diagnosed each year.

[Table of Contents](#)

Normal lungs (A) and lungs with IPF (B)



Graphic

The etiology of IPF remains unknown. IPF is a progressive disease, beginning with inflammation followed by fibrotic buildup as damaged epithelial cells surrounding the alveoli are replaced by fibroblasts, as shown above. Buildup of fibroblasts cause the lungs to thicken over time, becoming stiff and unable to properly function. In addition to complications from the disease itself, IPF can lead to other severe co-morbidities, including lung cancer, pulmonary embolisms, pneumonia or PH.

The most common symptoms of IPF are shortness of breath, persistent cough, fatigue, and weight loss, severely impacting quality of life. Given the non-specific nature of these symptoms, IPF is challenging to diagnose, particularly in the early stages of disease.

Current Treatments for IPF and Unmet Medical Need

Currently, there are two FDA-approved drugs for the treatment of IPF, Esbriet (pirfenidone) and Ofev (nintedanib).

Pirfenidone exhibits anti-fibrotic, anti-inflammatory and antioxidant properties through down-regulation of key pro-fibrotic growth factors including TGF- β , inhibition of inflammatory cytokines production and release and reduction of lipid peroxidation and oxidative stress. In Phase 3 trials, pirfenidone slowed disease progression and functional decline in patients with IPF and showed a reduced risk of mortality. Common adverse effects of pirfenidone include gastrointestinal intolerance such as nausea, diarrhea and dyspepsia and skin reactions, including rash and photosensitivity.

[Table of Contents](#)

Nintedanib is an intracellular inhibitor that targets multiple tyrosine kinase growth factor receptors (vascular endothelial growth factor receptors 1-3, fibroblast growth factor receptors 1-3, and platelet-derived growth factor receptors α and β). By inhibiting these receptors, nintedanib interferes with processes implicated in IPF pathogenesis, including proliferation and migration of lung fibroblasts, and differentiation of fibroblasts to myofibroblasts. Nintedanib may also have a mortality benefit. Its most frequent side effects are diarrhea and nausea.

Both drugs are recommended by the most recent treatment guidelines from 2015. These therapeutics slow disease progression, but do not offer a cure. The two-year mortality rate is 36% and 39% after treatment of nintedanib and pirfenidone respectively. Safety and tolerability concerns, which resulted in a 20% to 30% discontinuation rate due to side effects, limit therapeutic usage and there remains an unmet medical need for IPF patients. Despite these limitations, these two drugs have generated total sales of \$3.6 billion in 2020.

Overview of LPA1R Pathway and Target Biology

Lysophosphatidic acid ("LPA") is a bioactive lipid which exerts potent extracellular signaling through its interaction with several GPCRs, mediating important cellular responses, such as proliferation, migration, and cytoskeletal reorganization.

31

[Table of Contents](#)

LPA/LPA1R in IPF pathogenesis



Graphic

As shown above, upon injury to certain cells in the lung, LPA levels increase and activate LPA1R. In published third-party preclinical studies, LPA1R activation promoted pro-fibrotic processes, including accumulation of fibroblasts; genetic or PD inhibition of LPA1R attenuated bleomycin induced lung fibrosis by mediating fibroblast recruitment and vascular leak.

We believe that LPA1R has been clinically validated as a potential target based on proof-of-concept data from a third-party, third party, randomized, double blind, placebo-controlled Phase 2 trial of an LPA1R antagonist (BMS-986020) in patients with IPF. Patients in the 600mg BID cohort exhibited significantly slower rates of forced vital capacity decline from baseline to 26 weeks versus placebo. Although the compound was generally well tolerated, dose-related hepatobiliary toxicity in some patients led to early termination of the trial. After conducting additional toxicology investigations, BMS reported that hepatobiliary toxicity was likely caused by inhibition of bile acids efflux transporters such as Bile Salt Export Pump ("BSEP"). Second

35

[Table of Contents](#)

generation LPA1R antagonists (BMS-986278) with minimal BSEP inhibition by BMS are currently in clinical development.

We believe that LPA1R can also be used to treat progressive pulmonary fibrosis ("PPF"), which is defined as the presence of at least two of the three criteria, which are worsening respiratory symptoms, functional decline, and radiological progression in patients with interstitial lung

disease with radiological pulmonary fibrosis for known or unknown reasons other than IPF, within the previous year. A conditional recommendation has been made for nintedanib in the treatment of PPF, and further studies are needed for pirfenidone.

As illustrated below, we utilized the available protein structural information to collaborate with Schrödinger. After validation and customization with an initial set of compounds for retrospective analysis, Schrödinger's FEP was utilized and suggested potency in the prospective analysis. This customized model greatly expedited the iterative lead optimization process and helped us to achieve candidate selection efficiently.

[Table of Contents](#)

Iterative LPA1R Structure-Based Drug Discovery



Graphic

LTSE-2578 Preclinical Data

In an *in vivo* PK and PD study, mice were orally dosed with LTSE-2578 and challenged by LPA at one hour and at 12 hours after dosing. Plasma was collected at two minutes post-LPA challenge and histamine level was measured as a pharmacodynamics biomarker. As shown below, LTSE-2578 demonstrated reductions in histamine release at doses ≥ 0.06 mg/kg, as compared to approximately 45 ng/mL and approximately 201 ng/mL for BMS's first generation (BMS-986020) and second generation (BMS-986278) LPA1R antagonists, respectively.

[Table of Contents](#)

LTSE-2578 demonstrated dose dependent inhibition of histamine release



Graphic

33

[Table of Contents](#)

LTSE-2578 showed limited inhibition ($IC_{50} > 50 \mu M$) of efflux transporters including BSEP, MRP3 and MRP4, potentially reducing the likelihood of hepatobiliary toxicity caused by efflux transporter inhibition. IND-enabling

One month GLP toxicity studies of LTSE-2578 are ongoing with data expected in rats and dogs have been completed to enable the second half of 2023, upcoming first time in human study.

Overview of APJR Pathway and Target Biology

The apelinergic system plays a key role in the maintenance of vascular health and function through regulation of fibrosis, cell proliferation and inflammation. APJR is highly expressed in the pulmonary vascular endothelium and is upregulated on endothelial cells in IPF patients. Further, activation of the apelinergic system through APJR has been shown to protect endothelial cell survival, and is critical for regeneration of the small capillary blood vessels. These findings support the possibility that an APJR agonist may play a beneficial role in interstitial lung disease.

Apelin binding to APJR activates G-protein second messenger signaling and leads to reduced production of cyclic adenosine monophosphate ("cAMP"). Apelin binding to APJR also initiates a feedback loop that eventually downregulates apelin-APJR signaling by recruitment of β -arrestin and subsequent internalization of APJR. In addition, recruitment of β -arrestin triggers downstream pathways that induce vasorelaxation and cardiomyocyte hypertrophy. Therefore, the degree of activation by designed ligands of G-protein and β -arrestin signaling pathway may lead to both therapeutic benefit and undesirable effects.

37

[Table of Contents](#)

Importance of endothelial cells on pulmonary fibrosis



Graphic

As shown above, while epithelial cell damage and the inflammatory response are known contributors to fibrosis, recent studies have highlighted the importance of endothelial cells on pulmonary fibrosis. Microvascular injuries are observed in patients with pulmonary fibrosis. Persistent vascular leak may support a pro-inflammatory and pro-fibrotic environment. Endothelial senescence is found in the lung of IPF patients. Senescent endothelial cells could secrete factors that directly stimulate fibroblast activation. Targeting apelin pathway may promote capillary regeneration, ameliorate the inflammatory environment, and reduce endothelial senescence, in this way reducing lung fibrosis. Since an APJR agonist mainly targets endothelial cells, we believe it could be easily combined with the current standard of care, pirfenidone and nintedanib, which do not target the anti-fibrosis pathway from endothelial cells.

34

[Table](#) [Our APJR Program for the Treatment of](#) [Contents](#)Obesity

APJ is expressed in human and murine skeletal muscles. Apelin and APJ are widely distributed in the body and are involved in various physiological functions as blood pressure regulation. Depending on the cell type studied, APJ activation enhances extracellular signal-regulated kinases, AMPK, AKT, and p70S6 kinases and the inhibition of cyclic AMP (cAMP) production. Activation of these pathways would result in worthwhile increases in the protein content of skeletal muscles. Apelin has in fact proved beneficial in maintaining muscle and could potentially counteract age-associated atrophy.

We are evaluating ANPA-0073 which is Phase 2 ready, to be used in combination with weight loss medicines for selective or muscle-sparing weight loss.

ANPA-0073

We are [also](#) developing ANPA-0073, an investigational, oral, small molecule APJR agonist, for the treatment of IPF. ANPA-0073 is designed to suppress cAMP production through activation of a G-protein-mediated signaling without significant activation of the β -arrestin pathway in order to avoid APJ internalization, and thereby potentially avoid any desensitization effects of an unbiased APJR agonist. We conducted preclinical *in vitro* studies on our compounds and third-party compounds to assess arrestin signaling and internalization. As shown below, apelin peptide and clinically tested competitor compounds including AMG-986 and

38

[Table of Contents](#)

BMS-986224 are all non-biased APJR agonists in these *in vitro* studies, with low β -arrestin/cAMP and internalization/cAMP ratios. Our molecules, such as ANPA-0073 and ANPA-137, are designed to be biased with much higher β -arrestin/cAMP and internalization/cAMP ratios than apelin peptide and the competitor compounds shown below.

APJR biased agonism is a potential differentiator for ANPA-0073

COMPOUND ID	BIASED SELECTIVITY		BIASED SELECTIVITY	
	β -ARRESTIN		β -ARRESTIN	
	SIGNALING/cAMP	INTERNALIZATION/cAMP	SIGNALING/cAMP	INTERNALIZATION/cAMP
Apelin Peptide	1.33	1.47	1.33	1.47
AMG-986	0.86	1.00	0.86	1.00
BMS-986224	4.48	1.94	4.48	1.94
ANPA-0073	18.02	3,074	18.02	3,074
ANPA-137	28.20	1,411	28.20	1,411

ANPA-0073 Preclinical Data

In an *in vitro* study, ANPA-0073 demonstrated high potency in suppressing cAMP production through the G-protein-mediated signaling pathway with a half maximal excitatory concentration (EC50) value of less than 10 nM (n=15), but less potency in triggering the β -arrestin pathway and APJR internalization respectively. These data suggest ANPA-0073 is highly biased. The G-protein agonist potency of ANPA-0073 was similar across different species (rat, dog and monkey).

Anti-fibrosis effect of an APJ agonist ANPA-0137 was evaluated in bleomycin induced lung fibrosis model. Seven days after bleomycin challenges, mice received oral ANPA-137 for two weeks. ANPA-137 significantly reduced lung fibrosis Ashcroft scores and inflammatory cells infiltration into lung as quantified by inflammatory score as shown below.

35

[Table of Contents](#)

APJR agonist demonstrated anti-fibrosis efficacy in therapeutic IPF mouse model



Graphic

Furthermore, ANPA-137 also demonstrated anti-fibrotic activity in an *in vivo* bleomycin-induced rat lung fibrosis model. Similar to mouse bleomycin study design, seven days after bleomycin challenges, rats

39

received 15 mpk of oral ANPA-137 for two weeks. ANPA-137 significantly reduced lung fibrosis as quantified by Ashcroft score as shown below.

APJR agonist demonstrated anti-fibrosis efficacy in therapeutic IPF rat model



Graphic

ANPA-0073 Phase 1 Healthy Volunteer Trial Design

In September 2022, we completed a two-part, 96 subject, first-in-human Phase 1 SAD and MAD study for ANPA-0073 in 48 healthy adult volunteers between the ages of 18 and 55. The objective was to assess drug safety and PK. The first part of this study was a SAD study, involving eight cohorts of eight participants assigned to receive a single dose of ANPA-0073 or placebo in a 3:1 ratio. Doses from 2 mg to 600 mg across the eight cohorts were evaluated. The second part of the trial was a MAD study, including four cohorts of

36

eight subjects receiving sequential ascending doses of ANPA-0073 daily for seven days, increasing from 75 mg to 500 mg once daily. A schema of our Phase 1 study is presented below:

Schema of our ANPA-0073 Phase 1 study in healthy volunteers

ANPA-0073-01 Part A SAD Schema



Graphic

40

ANPA-0073-01 Part B MAD Schema



Graphic

ANPA-0073 Phase 1 Safety Data in Healthy Volunteers

ANPA-0073 was generally well tolerated at all dose levels administrated in the SAD and MAD parts of this Phase 1 study.

In the study, PK parameters of systemic exposure, C_{max} and AUC, increased with doses of ANPA-0073 across the dose range from 75 mg to 500 mg.



Graphic

In the SAD cohorts, no SAEs and no adverse changes in laboratory tests were observed. Among the AEs reported, five were considered moderate treatment emergent adverse events and the remaining were mild in severity. AEs did not result in any early terminations or subject discontinuations from participation in this study. No trial stopping criteria were met and no significant changes or trends in hematology, blood

chemistries, vital signs or electrocardiogram (“ECG”) measurements were noted. The following table shows all TEAEs that were reported:

ANPA-0073 Phase 1 SAD Treatment Emergent Adverse Events



Graphic

In the MAD portion of the Phase 1 study, no SAEs and no adverse changes in laboratory tests were observed. Among the AEs reported, twelve were considered moderate TEAEs and the remaining were mild in severity. AEs did not result in any early terminations or subject discontinuations from participation in this study. No trial stopping criteria were met and no significant changes or trends in hematology, blood

38

[Table of Contents](#)

chemistries, vital signs or ECG measurements were noted. The following table shows all TEAEs that were reported:

ANPA-0073 Phase 1 MAD Treatment Emergent Adverse Events



Graphic

A We will initiate the 26-week chronic GLP-toxicology studies in rats and 39-week studies in dogs that we believe will be required by regulatory agencies to continue dosing beyond 13 weeks in Phase I, Open-label Study to Evaluate the Relative Bioavailability of ANPA-0073 Capsule versus Tablet

2. We are planning to conduct a Phase 1 study to evaluate the relative oral bioavailability of two formulations of ANPA-0073 (tablet and capsule) using a 2-period, 2-sequence, 2-way crossover design. We expect this study to be an open-label study in 16 healthy male and female volunteers, aged 18 to 55 in Australia. After screening, we plan for subjects to be confined in the clinical unit from Day-1 to Day 10, and that each study subject will be enrolled and randomized into one of two treatment arms (n=8 per arm). Capsule and tablet formulations of ANPA-0073 will be administered as a single 200 mg (2 x 100 mg) dose in a fasted manner in two separate treatment periods: Day 1 (Period 1) and Day 7 (Period 2). We expect the sequence of administration (capsule → tablet vs. tablet → capsule) will differ between each treatment arm and that each treatment period will be separated by a 6-day washout interval.

Our APJR Program for the Treatment of PAH

We are also evaluating ANPA-0073 for the treatment of PAH. Despite existing treatment options for PAH, five-year mortality remains high. In a third-party clinical proof-of-concept study an acute infusion of an apelin agonist intravenously was shown to improve cardiac output. In our preclinical rat models, ANPA-0073 has shown increased cardiac output and mitigated the vascular remodeling that is characteristic of PAH. We believe that oral ANPA-0073 has the potential to provide therapeutic benefit through its novel mechanism of action, infrequent dosing, and lack of stringent administration requirements. selective or muscle-sparing weight loss.

PAH Overview

PAH Background

Pulmonary hypertension ("PH") is a group of diseases characterized by remodeling of the pulmonary vasculature that leads to a progressive elevation of blood pressure in the pulmonary circulation from a variety of causes. The World Health Organization ("WHO") has divided PH into five groups based on similarities in pathophysiology, clinical presentation, and therapeutic options as shown below.

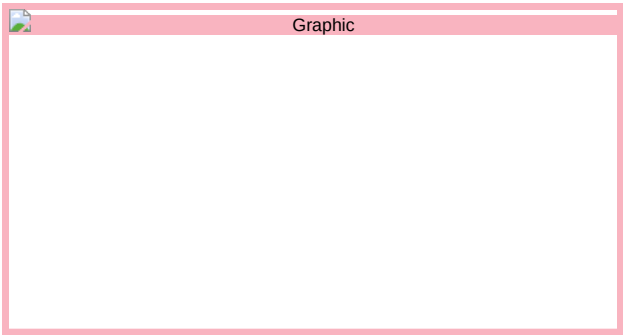
Table of Contents

WHO classification of pulmonary hypertension

- | | |
|---|--|
| 1 | Pulmonary arterial hypertension |
| 2 | Pulmonary hypertension secondary to left heart disease |
| 3 | Pulmonary hypertension from chronic lung diseases and/or hypoxia |
| 4 | Pulmonary hypertension due to pulmonary artery obstruction |
| 5 | Pulmonary hypertension from unexplained or multifactorial mechanisms |

PAH is a rare, progressive life-threatening disease characterized by elevated pressures in the pulmonary arteries, the blood vessels responsible for carrying deoxygenated blood from the heart to the lungs. This increase in pressure results from disordered proliferation of endothelial cells lining the lumen of pulmonary arteries, which causes a narrowing in blood vessel diameter and a consequent slowing of blood flow to the lungs. Over time, recruitment of inflammatory cells and cytokines stimulates fibrosis and further blood vessel remodeling, ultimately causing severe restrictions in blood flow. To overcome increased pulmonary arterial pressures, the right side of the heart must work harder in order to circulate blood through the lungs, causing excessive strain on the right ventricle. Left untreated, this leads to right ventricular hypertrophy and ultimately right heart failure, which can present with symptoms such as breathlessness, fatigue, chest pain, and abdominal distension.

Right ventricular hypertrophy and pulmonary arterial hypertension



As shown in the schematic of PAH pathology above, increased pulmonary vascular resistance is caused by cell proliferation in the pulmonary vessels that obstructs blood flow. Ultimately, this disease leads to right heart failure, resulting eventually in death. Therefore, treatments that can increase right heart contractility may have benefit.

In addition to the above classification based on physiologic mechanisms of PH, the WHO has also developed a functional classification of PH patients, including those with PAH, as shown below. Four functional classes categorize patient symptom severity and ability to carry out physical activity. Higher numbered functional classes indicate worsening symptoms and are associated with higher mortality. As patients in Class I are asymptomatic and generally not diagnosed and also cannot show clinical improvement, patients in Classes II–IV are generally studied in clinical trials of new therapeutic agents.

[Table of Contents](#)

WHO functional classification of pulmonary hypertension

WHO CLASS	DESCRIPTION
Class I	Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near syncope.
Class II	Patients with pulmonary hypertension resulting in a slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain or near syncope.
Class III	Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near syncope.
Class IV	Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

Prevalence of PAH and Unmet Medical Need

It is estimated that between 40,000 and 100,000 patients suffer from PAH worldwide, though the actual number is likely higher given underdiagnosis in developing countries. In the United States, the prevalence of PAH is 12 to 30 per million, and incidence is approximately 2.3 per million diagnosed annually.

Combined global sales for approved drugs for the treatment of PAH totaled approximately \$5.4 billion in 2020. While advances in the treatment of PAH have markedly improved median survival over the past two decades, patients still face significant disease burden and premature death. Patient survival of PAH remains poor at five years despite treatment advances and there is unmet medical need for new therapies beyond the standard of care.

Our current and future pipeline candidates could have broad applicability in other PH groups as well as more broadly in heart failure, which is estimated to affect approximately 26–64 million people worldwide.

Limitations of Current Treatments and Unmet Medical Need

The current standard of care for patients with PAH consist of three classes of vasodilators including phosphodiesterase 5 ("PDE5") inhibitors, endothelin receptor antagonists, and prostanoids. PDE5 inhibitors are often used in combination with ERAs as an early treatment strategy. In patients who fail to respond to combination therapy of an ERA and a PDE5 inhibitor, it is common practice to add a prostanoid which is also commonly used to treat patients with evidence of right heart failure. While existing treatments have led to significant improvements in time to clinical worsening and other composite endpoints in PAH patients, none directly alter the underlying disease process. The effect of vasodilation, while improving blood flow through the lungs, may eventually be overtaken by the worsening cellular proliferation and arterial remodeling underlying the condition.

Accordingly, we believe there is unmet medical need for therapies that are disease modifying and address more fundamental aspects of the disease.

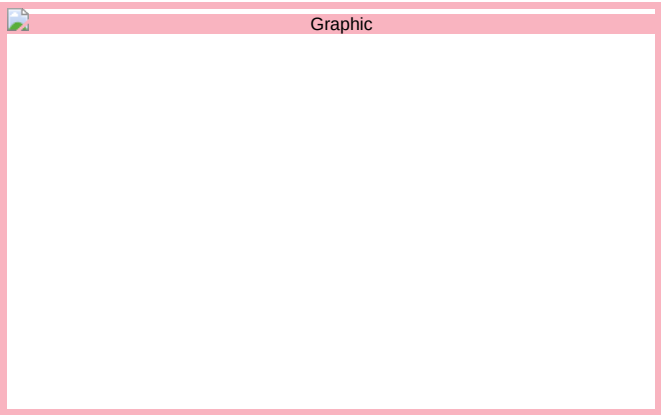
Apelin Receptor is a Clinically Validated and Highly Druggable Target

APJR is a GPCR with wide distribution throughout the human body.

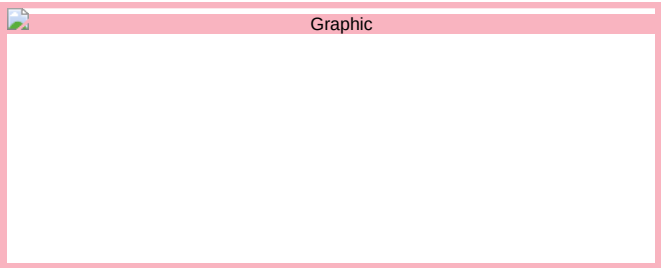
The expression patterns of apelin and APJR are consistent with their importance in cardiovascular and pulmonary diseases such as PAH. Apelin and APJR are expressed in several tissues, including those in the heart, lung, and blood vessels with expression observed in endothelial cells lining the blood vessels.

Activation of APJR pathways by its cognate peptide ligand, apelin, exerts pleiotropic effects in human biology, including inducing diverse physiological effects such as strengthening of cardiac contractility, vasodilation, angiogenesis, reducing vascular remodeling and regulation of energy metabolism and fluid homeostasis as shown below. We believe that the apelinergic signaling pathway will provide disease modifying effects in PAH through right ventricular protection and anti-pulmonary vessel remodeling.

Apelin Biology in human makes APJR an attractive target for PAH

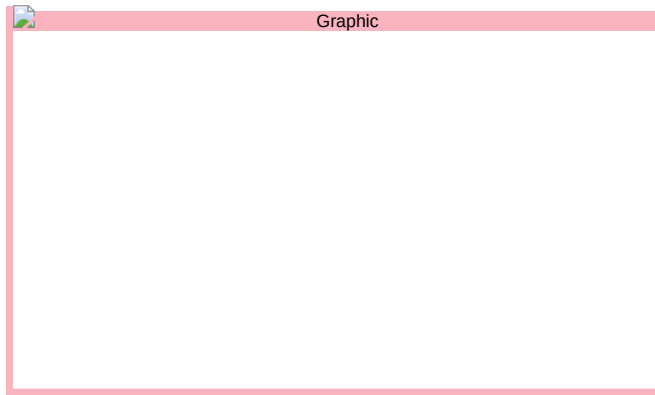


Apelin mRNA and protein levels in control and PAH lung samples



As shown above, the apelin expression level in the lung of PAH patients (IPAH) was dramatically reduced compared to the non-PAH (C) lung samples. Apelin signaling is implicated in PAH which can be induced in animal models by hypoxia, a condition which temporarily induces apelin expression.

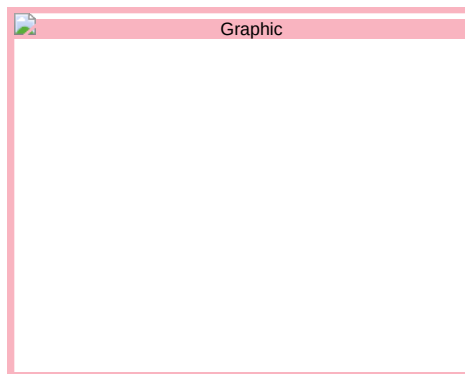
Apelin peptide reduced PVR and increased cardiac output without a change in heart rate or mean arterial pressure



As shown above, apelin has a role in cardiac function. In a published third-party clinical proof-of-concept study, intravenous infusion of apelin peptide in PAH patients provided a significant reduction in pulmonary vascular resistance and an increase in cardiac output without a change in heart rate or systemic vascular resistance. It was also observed that the effect was most prominent in the subgroup of patients receiving concomitant PDE5 inhibition.

Both biased and non-biased apelin analogs could increase cardiac contraction, while biased apelin analogs have limited effects on vasorelaxation and systemic blood pressure reduction. These suggest that the inotropic efficacy mainly signals through G-protein pathway, while β -arrestin signaling pathway correlates with hypotensive effect as shown below.

APJR agonist activity on β -arrestin recruitment and its correlation with hypotensive effect.



43

[Table of Contents](#)

We believe that a biased APJR agonist as compared to a non-biased agonist has the potential to maintain long-term cardiac output and stroke volume improvement while avoiding β -arrestin related hypotensive effect and mechanical stress induced cardiac hypertrophy.

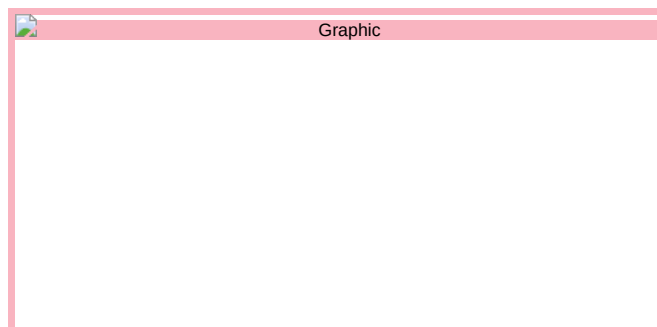
Our Solution: Small Molecule Biased APJR Agonist

As described above, we are developing ANPA-0073, a novel orally-available biased APJR agonist which is designed to suppress cAMP production through activation of a G-protein-mediated signaling without significant activation of the β -arrestin pathway in order to avoid APJR internalization.

We believe that ANPA-0073 has the potential to be a differentiated and disease-modifying therapeutic agent and it is designed to provide the following potential advantages:

- Orally-available with improved cardiac contractility, increased stroke volume and right ventricular cardiac output leading to increased survival;
- Biased agonism that avoids down regulation due to APJR internalization;
- Disease-modifying effect through decreased vascular remodeling; and
- Limited effect on systemic blood pressure, avoiding hypotension.

ANPA-0073 did not change mean arterial blood pressure in a rat telemetry study



One way ANOVA analysis; **** $p < 0.0001$ compared to vehicle

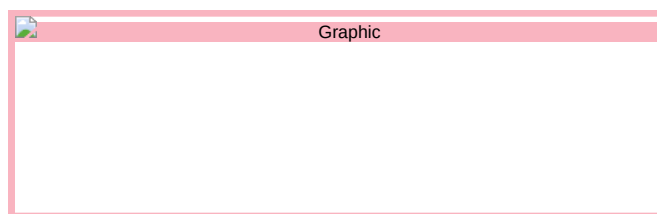
As shown above, in a rat telemetry model, a non-biased apelin peptide demonstrated an acute decrease in mean arterial pressure as expected, whereas the biased molecule, ANPA-0073, did not.

ANPA-0073 has demonstrated promising activity in multiple animal models. In five different studies using monocrotaline ("MCT") induced rat models of PAH, daily oral doses of ANPA-0073 reduced right ventricular systolic pressure, right ventricular hypertrophy index, and percentage of pulmonary artery wall thickness ("PAWT"), but increased right ventricular ejection fraction. As shown below, ANPA-0073 treatment resulted in reduced pulmonary artery pressure and increased cardiac function.

44

[Table of Contents](#)

Treatment with sildenafil or an ANPA-0073 in an MCT rat model of PAH



One way ANOVA analysis; * $p < 0.05$, ** $p < 0.01$, **** $p < 0.0001$ compared to vehicle

In summary, in a published third-party clinical proof-of-concept study, an intravenous infusion of apelin has demonstrated increased cardiac output, especially in combination with the PAH standard of care therapy, sildenafil. In the MCT rat model of PAH, our biased apelin agonists showed increased cardiac stroke volume and cardiac output without impacting heart rate, and also mitigation of PAH-induced vascular remodeling. Together, these data suggest that an orally-available, biased apelin agonist, such as ANPA-0073, may have potential as a treatment for PAH, providing benefits differentiated from current standard of care therapies.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate

without infringing the proprietary rights of others, and in part on our ability to prevent others from infringing our proprietary rights. A comprehensive

42

[Table of Contents](#)

discussion on risks relating to intellectual property is provided under Part I. Item 1A. "Risk Factors—Risks Related to Our Intellectual Property."

For our GLP-1R program, as of **December 31, 2022** **December 31, 2023**, our wholly-owned subsidiary Gasherbrum Bio, Inc., is the sole owner of one granted U.S. patent and **five 11** pending U.S. patent applications, **16 14** Patent Cooperation Treaty ("PCT"), applications, and **42 94** pending foreign patent applications in Argentina, **the** African Regional Intellectual Property Organization ("ARIPO"), Australia, Brazil, Canada, Chile, the People's Republic of China ("PRC"), Colombia, Costa Rica, Dominican Republic, Egypt, **the** Eurasian Patent Office ("**EAPO**" (**the** "**EAPO**"), **the** European Patent Office ("**EPO**" (**the** "**EPO**"), Guatemala, **Hong Kong**, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Panama, Peru, Philippines, Saudi Arabia, Singapore, Thailand, Taiwan, Ukraine, Vietnam, and South Africa. These patent applications, to the extent they issue (or in the case of priority applications, if issued from future non-provisional applications that we file), are expected to expire between 2041 and **2043, 2044**, without accounting for potentially available patent term adjustments or extensions. These patent applications relate to compositions of matter of heterocyclic GLP-1 agonists, including GSK-1290 and its analogs, solid forms and methods of treating conditions associated with GLP-1R activity. We intend to strengthen the patent protection of our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations through additional patent application filings.

For our **oral small molecule** APJR program, as of **December 31, 2022** **December 31, 2023**, our wholly-owned subsidiary Annapurna Bio, Inc. is the sole owner of **one two** granted U.S. **patent patents** and **two three** pending U.S. patent applications, one PCT application, **one granted European patent** and **22 24** pending foreign patent applications in Argentina, Australia, Brazil, Canada, the PRC, **the** EAPO, **the** EPO, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore, Taiwan, and South Africa relating to compounds and compositions of matter for treating conditions associated with Apelin receptor activity, including ANPA-0073 and its analogs, solid forms and methods of treating conditions associated with Apelin receptor activity. Any patents issuing from these patent applications (or in the case of priority applications, if issued from future non-provisional applications that we file) are expected to expire between 2039 and 2043, without accounting for potentially available patent term adjustments or extensions.

45

[Table of Contents](#)

For our LPA1R program, as of **December 31, 2022** **December 31, 2023**, our wholly-owned subsidiary Lhotse Bio, Inc. ("Lhotse") is the sole owner of **three** pending U.S. **patent applications**, four PCT applications and **two seven** pending foreign patent applications in Argentina, **the** PRC, **the** EPO, Japan, and Taiwan relating to compounds and compositions of matter for treating conditions associated with LPA receptor activity, including LTSE-2578 and **their its** analogs, and methods of treating conditions associated with LPA receptor activity. Any patents issuing from these patent applications (or in the case of priority applications, if issued from future non-provisional applications that we file) are expected to expire between 2041 and **2043, 2044**, without accounting for potentially available patent term adjustments or extensions.

For our oral small molecule Amylin program, as of **December 31, 2023**, our wholly-owned subsidiary Aconcagua Bio, Inc. ("Aconcagua") is the sole owner of **two** PCT applications relating to compounds and compositions of matter for treating conditions associated with Amylin receptor activity and methods of treating conditions associated with Amylin receptor activity. Any patents issuing from these patent applications (or in the case of priority applications, if issued from future non-provisional applications that we file) are expected to expire in **2044**, without accounting for potentially available patent term adjustments or extensions.

In addition to patent protection, we also rely on trade secrets, know-how, trademarks, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us.

43

[Table of Contents](#)

However, such confidentiality agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see Part I. Item 1A. "Risk Factors — Risks Related to Our Intellectual Property."

Lhotse Collaboration Agreement with Schrödinger, LLC

In October 2020, Lhotse, our wholly-owned subsidiary, entered into a collaboration agreement with Schrödinger (the "Lhotse-Schrödinger Agreement") 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 **December 31, 2022** **December 31, 2023**, we have paid to Schrödinger an aggregate of \$0.8 million. If Lhotse develops and commercializes a product containing a compound ("Collaboration Compound") that is discovered or developed under the Lhotse-Schrödinger Agreement ("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 in the low single digit range on aggregate worldwide net sales of all 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 owned 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 ("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

46

[Table of Contents](#)

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.

Aconcagua Collaboration Agreement with Schrödinger

In November 2023, Aconcagua, our wholly-owned subsidiary, entered into a collaboration agreement (the "Aconcagua-Schrödinger Agreement") with Schrödinger to discover and develop novel, small molecule modulators of a specific target. Under the Aconcagua-Schrödinger Agreement, Schrödinger is obligated to provide computational modeling and design support, including by using its technology platform to perform virtual screens, and Aconcagua is obligated to provide day-to-day chemistry and biology support. Pursuant to the Aconcagua-Schrödinger Agreement, a joint steering committee comprised of representatives from both parties oversees the research performed under the agreement. During the term of the Aconcagua-Schrödinger Agreement or if longer, for a specified number of years after the effective date of the Aconcagua-Schrödinger Agreement, Schrödinger is obligated, subject to certain exceptions, to work exclusively with Aconcagua on the design, research, development and commercialization of compounds that inhibit the target. Aconcagua will solely own the research results, work product, inventions and other intellectual property

44

[Table of Contents](#)

generated under the Aconcagua-Schrödinger Agreement other than improvements to Schrödinger's background intellectual property.

During the term of the Aconcagua-Schrödinger Agreement, Aconcagua is obligated to pay Schrödinger a monthly active program payment in the low six digits, which payment includes fees payable for certain Schrödinger software employed in the Collaboration, and as of December 31, 2023, we have paid to Schrödinger an aggregate of \$0.3 million. If Aconcagua develops and commercializes a product containing a compound ("Aconcagua Collaboration Compound") that is discovered or developed under the Aconcagua-Schrödinger Agreement or a derivative thereof ("Aconcagua Collaboration Product"), Aconcagua is obligated to pay Schrödinger development, regulatory and commercialization milestone payments of up to an aggregate of \$89.0 million for the first Aconcagua Collaboration Product to achieve a particular milestone event, regardless of the number of Aconcagua Collaboration Products that reach such milestones. Aconcagua will also be obligated to pay Schrödinger tiered royalties in the low single digit range on aggregate worldwide net sales of all Aconcagua Collaboration Products, subject to specified reductions and offsets. Aconcagua's obligation to pay royalties to Schrödinger will expire on a Aconcagua Collaboration Product-by- Aconcagua Collaboration Product and country-by-country basis on the later of (i) the expiration of the last-to-expire Aconcagua owned patent claim covering the composition of matter of the Aconcagua Collaboration Compound contained in such Aconcagua Collaboration Product in such country and (ii) ten years after the first commercial sale of such Aconcagua Collaboration Product in such country ("Aconcagua Royalty Term").

Unless terminated earlier, the Aconcagua-Schrödinger Agreement will continue for three years, subject to extension by mutual written agreement of the parties. Either party may terminate the Aconcagua-Schrödinger Agreement for convenience after a specified period or for the other party's uncured material breach. Aconcagua's obligation to make milestone and royalty payments (subject to the Aconcagua Royalty Term) to Schrödinger continues after the expiration or termination of the Aconcagua-Schrödinger Agreement, unless the Aconcagua-Schrödinger Agreement is terminated under specified circumstances.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates and currently have no immediate plans to build our own clinical or commercial scale manufacturing capabilities. We currently engage with third-party contract manufacturing organizations ("CMOs") in multiple geographies for the manufacture of our product candidates. We rely on and expect to continue to engage third-party manufacturers for the production of both drug substance and finished drug product. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long-term supply arrangements in place. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur some delay in identifying and qualifying such replacements.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If any of our product candidates are approved for the indications for which we expect to conduct clinical trials, they will compete with the foregoing therapies and currently marketed drugs, as well as any drugs potentially in development. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition, and availability of reimbursement.

Despite significant biopharmaceutical industry investment, no oral small molecule therapy targeting GLP-1R has been approved for the treatment of diabetes or obesity. We are aware of GLP-1R small molecules in

45

[Table of Contents](#)

development by [Eccogene \(licensed by Astrazeneca in November 2023\)](#), [Carmot Therapeutics \(acquired by Roche in January 2024\)](#), [Terns Pharmaceuticals](#), [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 aware of other GLP-1R plus dual/tri incretin targeting peptides in development by [Eli Lilly](#), [Jiangsu Hansoh Pharmaceutical Group Co., Ltd.](#), [Boehringer Ingelheim](#), [Altimune, Inc.](#), [Carmot Therapeutics, Inc.](#), and [Sciwind Biosciences Co., Ltd.](#) In addition, there are a number of companies developing product candidates for diabetes and obesity utilizing approaches with different mechanisms of action, including but not limited to sodium-glucose cotransporter-2 inhibitors.

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 [Bristol Myers Squibb \("BMS"\)](#) have APJR targeted product candidates for heart failure. In addition, there are a number of companies developing product candidates for PAH utilizing approaches with different mechanisms of action, including but not limited to [FibroGen, Inc.](#), [Galapagos NV](#), [Galecto, Inc.](#), [Pliant Therapeutics, Inc.](#), [Gilead Sciences, Inc.](#), [Roche Holding AG](#) and [Boehringer Ingelheim](#).

We are aware of LPA1R targeted product candidates in development for IPF by [BMS](#), [Horizon Therapeutics plc \(acquired by Amgen in October 2023\)](#), and [DJS Antibodies Ltd](#); and myelin restoration and neuroinflammation by [Pipeline Therapeutics](#). In addition, there are a number of companies developing product candidates for IPF utilizing approaches with different mechanisms of action, including [Roche Holding AG](#) and [Boehringer Ingelheim](#).

47

[Table of Contents](#)

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal or sensitive information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the European Union General Data Protection Regulation ("EU GDPR") imposes strict requirements for processing the personal data of individuals within

46

[Table of Contents](#)

the European Economic Area ("EEA"). Companies that must comply with the EU GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom ("UK") GDPR ("UK GDPR") which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR relating to fines up to the greater of £17.5 million or 4% of global turnover. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Regulation

Government Regulation of Pharmaceutical Product Development and Approval

U.S. Regulation of Pharmaceutical Product Development and Approval

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining marketing approvals and the subsequent compliance with appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Our drug candidates must be approved by the FDA through the New Drug Application ("NDA") NDA process before they

48

[Table of Contents](#)

may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's good laboratory practices ("GLP") regulations;
- submission to the FDA of an Investigational IND which must become effective before human clinical trials may begin;
- approval by an institutional review board ("IRB") or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable good clinical practices ("GCPs") and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug product for its proposed indication;
- preparation and submission to the FDA of an NDA together with payment of user fees;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- review by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced to assess compliance with the FDA's current Good Manufacturing Practices ("cGMP");
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and Clinical Trials

The preclinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out

47

[Table of Contents](#)

non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the preclinical tests must comply with federal regulations, including GLPs where applicable. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the drug product to human subjects or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which establish standards for conducting, recording data from, and reporting the results of clinical trials, and are intended to assure that the rights, safety, and well-being of study participants are protected. GCPs also include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted

49

[Table of Contents](#)

under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Further, each clinical trial must be reviewed and approved by each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits.

The IRB also reviews and approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase I, Phase II and Phase III clinical trials.

- **Phase I:** The drug is initially introduced into a small number of healthy volunteers or patients with the target disease or condition who are initially exposed to a single dose and then multiple doses of

48

[Table of Contents](#)

the drug candidate. These studies are designed to assess the metabolism, pharmacologic action, dosage tolerance, side effects associated with increasing doses, and safety of the drug, and if possible, to gain early evidence on effectiveness.

- **Phase II:** The drug is administered to a limited patient population with a specified disease or condition to evaluate optimal dosage and dosing schedule. At the same time, safety and further PK and PD information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.
- **Phase III:** The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall benefit/risk profile of the drug and provide an adequate basis for drug approval and labeling of the drug product.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of NDA approval.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an

50

institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and FDA Review Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of non-clinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. Under the Prescription Drug User Fee Act, as amended ("PDUFA") each NDA must be accompanied by an application user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual prescription drug program fee for human drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing"

decision after it the application is submitted. The FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality and purity.

The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may re-analyze clinical trial data and may also audit data from clinical trials to ensure compliance with GCP requirements.

After the FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter ("CRL") An approval letter authorizes commercial marketing of the

drug with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the

51

[Table of Contents](#)

application is not ready for approval. A CRL usually describes all of the specific deficiencies in the NDA identified by the FDA. The CRL may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a drug receives marketing approval, such approval will be granted for particular indications and may be significantly limited to specific diseases, dosages, or patient populations. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require so-called Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of a drug or biological product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Pediatric Trials

Under the Pediatric Research Equity Act, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-Phase II

50

[Table of Contents](#)

meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will publicly disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product

52

[Table of Contents](#)

exclusivity, meaning that the FDA may not approve any other applications for the same product for the same indication for seven years, including a full NDA, except in certain limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

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 designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Marketing Requirements

Following approval of a new drug, the NDA sponsor and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements. Modifications or enhancements to the drug or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

FDA regulations also require that approved drug products be manufactured in specific facilities identified in the approved application for marketing and in accordance with cGMP. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any

51

[Table of Contents](#)

deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;

53

[Table of Contents](#)

- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the acceptance by the FDA for review, or the approval, of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or

52

[Table of Contents](#)

an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original reference drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be accepted for review after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA for the reference drug.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, such as new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving abbreviated NDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use.

Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

54

[Table of Contents](#)

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the Department of Health and Human Services, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, the activities of pharmaceutical manufacturers are subject to federal and state laws designed to prevent fraud and abuse in the healthcare industry. The laws generally limit financial interactions between manufacturers and health care providers or other participants in the healthcare industry and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation.

Pharmaceutical manufacturers are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require tracking and reporting of certain drug prices. Manufacturers are subject to fines and other penalties if such prices are not reported accurately. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects manufacturers to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, civil monetary or other penalties, injunctions, recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, additional regulatory oversight and integrity monitoring, exclusion from participation in government healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with

53

FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Chinese Regulation of Pharmaceutical Product Development and Approval

Since China's entry into the World Trade Organization in 2001, the Chinese government has made significant efforts to standardize regulations, develop its pharmaceutical regulatory system and strengthen intellectual property protection.

In October 2017, China's drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Office of the Communist Party of China Central Committee jointly issued the Opinion on Deepening the Reform of the Regulatory Approval System to Encourage Innovation in Drugs and Medical Devices, or the Innovation Opinion, which is a mandatory plan to further reform the review and approval system and to encourage the innovation of drugs and medical devices. Under the Innovation Opinion and other recent reforms, the expedited programs and other advantages encourage drug manufacturers to seek marketing approval in China first and to develop drugs in high priority disease areas, such as oncology or rare disease.

To implement the regulatory reform introduced by the Innovation Opinion, the Standing Committee of the National People's Congress of the PRC ("SCNPC") and the National Medical Products Administration ("NMPA") have **recently** revised the fundamental laws, regulations and rules governing pharmaceutical products and the pharmaceutical industry, including the amendment of the framework law known as the People's Republic of China Drug Administration Law ("PRC Drug Administration Law"), which became

effective on December 1, 2019. The State Administration for Market Regulation ("SAMR") has promulgated two key implementing regulations for the PRC Drug Administration Law: (i) the amended Administrative Measures for Drug Registration and (ii) the amended Measures on the Supervision and Administration of the Manufacture of Drugs. Both regulations took effect on July 1, 2020.

Rest of the World Regulation of Pharmaceutical Product Development and Approval

For other countries outside of Asia and the United States, such as countries in Europe, Latin America or other parts of Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with applicable GCP requirements and the applicable regulatory requirements and ethical principles.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws

Other U.S. Healthcare Laws

We may also be subject to healthcare regulation and enforcement by the U.S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and transparency laws, such as the following:

- federal Anti-Kickback Statute, which prohibit, among other things, persons from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

[Table of Contents](#)

- federal false claims laws, including the False Claim Act and the Civil Monetary Penalties Law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers payors that are false or fraudulent. In addition, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the Federal Food, Drug, and Cosmetic Act ("FDCA"), which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the federal 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 certain exceptions) to report annually to the CMS, information related to payments or other transfers of value made to physicians (defined to include

[Table of Contents](#)

doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," and their subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, payor, including private insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

We may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Efforts to ensure that our activities comply with applicable healthcare laws may involve substantial costs. Many of these laws and their implementing regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we could be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, additional regulatory oversight and integrity monitoring, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

[Table of Contents](#)

Coverage and Reimbursement

U.S. Coverage and Reimbursement

Successful sales of our drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly. Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage).

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could have a material adverse effect on our sales, results of operations and financial condition.

[Table of Contents](#)

General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a drug candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or any significant taxes or fees.

U.S. Health Care Reform

The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, in March 2010, the Affordable Care Act ("ACA") was passed which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. There have been judicial, Congressional and executive branch challenges to certain aspects of the ACA, including efforts to repeal or replace certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. 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.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state

56

[Table of Contents](#)

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 products. For example, 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, 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation program is currently subject to legal challenges. 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 CMS Innovation Center 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. Further, on December 7, 2023, the Biden administration released announced an additional executive order on October 14, 2022 initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, directing HHS the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to report on how exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries, framework.

Other Significant Chinese Regulation Affecting Our Business Activities in China

Chinese Regulation of Foreign Investment

The establishment, operation and management of corporate entities in China are governed by the Company Law of the People's Republic of China (the "PRC Company Law"), which was adopted by the SCNPC in December 1993, implemented in July 1994, and subsequently amended in December 1999, August 2004, October 2005, December 2013 and October 2018. Under the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies. Pursuant to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail.

58

[Table](#) [The most recent amendment of Contents](#) the PRC Company Law was adopted in December 2023 and will come into effect on July 1, 2024, which introduced multiple updates to the current PRC Company Law with regard to, among others, the capital contribution liability, corporate governance structure and responsibilities of directors, supervisors, senior managers, controlling shareholders and actual controllers.

Investment activities in China by foreign investors are governed by the Guiding Foreign Investment Direction, which was promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, and the latest Special Administrative Measures (Negative List) for

Foreign Investment Access (2021) (the "Negative List"), which was promulgated by the Ministry of Commerce of the People's Republic of China ("MOFCOM"), and National Development and Reform Commission ("NDRC"), on December 27, 2021 and took effect on January 1, 2022. The Negative List set out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 12 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

The Foreign Investment Law of the People's Republic of China (the "Foreign Investment Law") was promulgated by the National People's Congress ("NPC") in March 2019 and **become** **became** effective in January 2020. After the Foreign Investment Law came into force, the Law on Wholly Foreign-Owned Enterprises of the People's Republic of China, the Law on Sino-foreign Equity Joint Ventures of the People's Republic of China and the Law on Sino-foreign Contractual Joint Ventures of the People's Republic of China

[Table of Contents](#)

have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as foreign investors) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law, including: (i) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; (ii) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; (iii) investing by foreign investors in new projects in China alone or jointly with other investors; (iv) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law, which came into effect in January 2020. After the Regulations on Implementing the Foreign Investment Law came into effect, the Regulation on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law, Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise, the Regulations on Implementing the Wholly Foreign-Owned Enterprise Law and the Regulations on Implementing the Sino-Foreign Cooperative Joint Venture Enterprise Law have been repealed simultaneously.

In December 2019, the MOFCOM and the SAMR issued the Measures for the Reporting of Foreign Investment Information, which came into effect in January 2020. After the Measures for the Reporting of Foreign Investment Information came into effect, the Interim Measures on the Administration of Filing for Establishment and Change of Foreign Investment Enterprises has been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities pursuant to these measures.

Chinese Regulation of Commercial Bribery

Pursuant to specific provisions in the amended People's Republic of China Anti-Unfair Competition Law, commercial bribery is prohibited. Both the bribe giver and bribe recipient are subject to civil and criminal liability. Further, pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry, which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for the establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant Chinese government authorities merely by virtue of having contractual relationships with distributors or third-party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third-party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no

legal obligation to monitor the operating activities of its distributors and third-party promoters, and it will not be subject to penalties or sanctions by relevant Chinese government authorities as a result of failure to monitor their operating activities.

Chinese Regulation of Product Liability

In addition to the strict new drug approval process, certain Chinese laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in China. Under current Chinese law, manufacturers and vendors of defective products in China may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the People's Republic of China ("PRC Civil Law") promulgated on April 12, 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. The Civil Code of the People's Republic of China ("PRC Civil Code"), which was promulgated in May 2020 and became effective on January 1, 2021, amalgamates and replaces a series of specialized laws in civil law area, including the PRC Civil Law. The rules on product liability in the PRC Civil Code remain consistent with the rules in the PRC Civil Law.

58

On February 22, 1993, the Product Quality Law of the People's Republic of China ("Product Quality Law") was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised on July 8, 2000, August 27, 2009 and December 29, 2018 respectively. Pursuant to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the People's Republic of China on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. According to which, all business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

Chinese Tort Law

Under the Tort Law of the People's Republic of China ("Tort Law"), which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as the issuance of a warning, or the recall of products in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages. The PRC Civil Code amalgamated and replaced the Tort Law effective January 1, 2021. The rules on tort in the PRC Civil Code are generally consistent with the Tort Law.

Chinese Regulation of Intellectual Property Rights

China has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names.

60

[Table of Contents](#)

Patents

Pursuant to the Patent Law of the People's Republic of China (the "PRC Patent Law"), most recently amended in December 2008 and October 2020, and its implementation rules, most recently amended in January 2010, 2024, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten and fifteen years, respectively, from the date of application. The PRC Patent Law adopts the principle of "first-to-file" system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no

[Table of Contents](#)

identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the China National Intellectual Property Administration ("CNIPA"). Normally, the CNIPA publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the CNIPA for a substantive examination within three years from the date of application.

Article 19 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the CNIPA for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. **This added requirement of confidential examination by the CNIPA has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China.** The PRC Patent Law also sets up the framework and adds the provisions for patent linkage and patent term extension.

Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offenses such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner's patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent

administration authority. A Chinese court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license.

61

[Table of Contents](#)

Statutory damages may be awarded in the circumstances where the damages cannot be determined by the calculation standards referenced above. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

The most recent amendment to the PRC Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, describes the general principles of linking generic drug applications to pharmaceutical patent protection, also known as Patent Linkage. In July 2021, the NMPA and the CNIPA jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) ("Measures on Patent Linkage"), providing an operating mechanism for Patent Linkage. Upon notification of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after the Center for Drug Evaluation ("CDE's") publication and must submit a copy of the case acceptance notification to the CDE within 15 working days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. For chemical drugs, the NMPA would initiate a nine-month approval stay period upon notification. If the patentee or the interested person cannot secure a favorable court judgment or a decision from the CNIPA within the nine-month period, the NMPA can grant marketing authorization to the generic applicant after the nine-month period expires.

60

[Table of Contents](#)

Medical Patent Compulsory License

According to the PRC Patent Law, for the purpose of public health, the CNIPA may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which China has acceded.

Exemptions for Unlicensed Manufacture, Use, Sale or Import of Patented Products

The PRC Patent Law provides five exceptions permitting the unauthorized manufacture, use, sale or import of patented products. None of following circumstances are deemed an infringement of the patent rights, and any person may manufacture, use, sell or import patented products without authorization granted by the patent owner as follows:

- Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual;
- Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application and continues to manufacture such product or use such method only within the original scope;
- Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of China and uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity;

- Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or
- Any person who manufactures, uses or imports patented drug or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures, uses or imports patented drugs or patented medical equipment for the abovementioned person.

However, if patented drugs are utilized on the ground of exemptions for unauthorized manufacture, use, sale or import of patented drugs prescribed in PRC Patent Law, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner.

62

[Table of Contents](#)

Trade Secrets

According to the People's Republic of China Anti-Unfair Competition Law promulgated by the SCNPC on September 2, 1993, as amended on November 4, 2017 and on April 23, 2019 (collectively, the "PRC Anti-Unfair Competition Law"), the term "trade secrets" refers to technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders.

Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of such illegal conduct but nevertheless obtains, uses or discloses trade secrets of others trade secrets, the third party may be deemed to have committed a misappropriation of the others' trade secrets.

61

[Table of Contents](#)

Trademarks and Domain Names

Trademarks. According to the Trademark Law of the People's Republic of China, promulgated by the SCNPC in August 1982, as amended in February 1993, October 2001, August 2013 and April 2019 and its implementation rules (collectively, the "Trademark Law"), the Trademark Office of the National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout China. The Trademark Law has adopted a "first-to-file" principle with respect to trademark registration.

Domain Names. Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology in August 2017 and effective November 2017. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of Chinese internet domain names.

Chinese Regulation of Labor Protection

Under the Labor Law of the People's Republic of China, effective on January 1, 1995 and subsequently amended on August 27, 2009 and December 29, 2018, the Employment Contract Law of the People's Republic of China, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008,

employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the People's Republic of China.

Pursuant to the Law of Manufacturing Safety of the People's Republic of China effective on November 1, 2002 and amended on August 27, 2009, August 31, 2014 and June 10, 2021, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards, and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production

63

[Table of Contents](#)

safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable Chinese laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011 and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds, which became effective on January 22, 1999 and amended on March 24, 2019, Interim Measures concerning the Maternity Insurance of Employees, which became effective on January 1, 1995, and the Regulations on Work-related Injury Insurance, which became effective on January 1, 2004 and was subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Regulations Relating to Foreign Exchange Registration of Offshore Investment by Chinese Residents

In July 2014, the State Administration of Foreign Exchange ("SAFE"), issued SAFE Circular 37 and its implementation guidelines. Pursuant to SAFE Circular 37 and its implementation guidelines, residents of

62

[Table of Contents](#)

China (including Chinese institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle ("SPV"), directly established or indirectly controlled by Chinese residents for the purposes of offshore investment and financing with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such Chinese residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a Chinese resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the Chinese individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV. Failure to comply with the registration procedures set forth in the SAFE Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of

foreign exchange capital, and may also subject relevant onshore companies or Chinese residents to penalties under Chinese foreign exchange administration regulations.

Regulations Relating to Employee Stock Incentive Plan

In February 2012, 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 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 plan are subject to such regulation. In addition, the State Taxation Administration of the PRC, or SAT, has issued circulars concerning employee stock options or restricted shares. Under these circulars, employees working in China who exercise stock options, or whose restricted shares vest, will be subject to Chinese individual income tax ("IIT"). The Chinese subsidiaries of an overseas listed company have obligations to file documents related to employee stock options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their stock options or restricted shares. If the employees fail to pay, or the Chinese subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the Chinese subsidiaries may face sanctions imposed by the tax authorities or other Chinese government authorities.

64

Table of Contents

Regulations Relating to Dividend Distribution

Pursuant to the PRC Company Law and Foreign Investment Law, and Regulations on Implementing the Foreign Investment Law of the People's Republic of China, foreign investors may freely remit into or out of China, in RMB or any other foreign currency, their capital contributions, profits, capital gains, income from asset disposal, intellectual property royalties, lawfully acquired compensation, indemnity or liquidation income and so on within the territory of China.

In January 2017, SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

63

Table of Contents

Regulations Relating to Foreign Exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required

where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises ("SAFE Circular 142"), regulating the conversion by a foreign-invested enterprise of foreign currency-registered capital into RMB by restricting how the converted RMB may be used. SAFE Circular 142 provides that the RMB capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within China. SAFE also strengthened its oversight of the flow and use of the RMB capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such RMB capital may not be changed without SAFE's approval, and such RMB capital may not in any case be used to repay RMB loans if the proceeds of such loans have not been used. In March 2015, SAFE issued the Circular of the State Administration of Foreign Exchange on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises ("SAFE Circular 19"), which became effective and replaced SAFE Circular 142 on June 1, 2015. Although SAFE Circular 19 allows for the use of RMB converted from the foreign currency- denominated capital for equity investments in China, the restrictions continue to apply as to foreign-invested enterprises' use of the converted RMB for purposes beyond the business scope, for entrusted loans or for inter-company RMB loans. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account ("SAFE Circular 16"), effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to unassociated enterprises. On December 4, 2023, SAFE promulgated the Notice of the State Administration of Foreign Exchange on Further Deepening the Reform and Promoting Facilitation of Cross-border Trade and Investment ("SAFE Circular 28"), which further updates the restrictions on use of RMB converted from the foreign currency- denominated capital. Violations of SAFE Circular 19, SAFE Circular 16 or SAFE Circular 16 28 could result in administrative penalties.

The Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment was promulgated by SAFE in November 2012 and amended in May 2015, which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of

65

[Table of Contents](#)

various special purpose foreign exchange accounts (e.g., pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in China (e.g., profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of foreign exchange as a result of capital reduction, liquidation, early repatriation or share transfer in a foreign-invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in China shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches.

In February 2015, SAFE promulgated the Circular on Further Simplifying and Improving the Policies Concerning Foreign Exchange Control on Direct Investment ("SAFE Circular 13"), which took effect on June 1, 2015.

64

[Table of Contents](#)

June 1, 2015. SAFE Circular 13 delegates the authority to enforce the foreign exchange registration in connection with the inbound and outbound direct investment under relevant SAFE rules to certain banks and therefore further simplifies the foreign exchange registration procedures for inbound and outbound direct investment.

Regulations on Securities Offering and Listing Outside of China

On February 17, 2023, the CSRC promulgated 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 which **will come** **came** into effect on March 31, 2023 to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form.

The Trial Measures and supporting guidelines apply to overseas offerings by domestic companies of equity shares, depositary receipts, convertible corporate bonds, or other equity-like securities, and overseas listing of the securities for trading. Both direct and indirect overseas securities offering and listing by domestic companies would be regulated, of which the former refers to securities offering and listing in an overseas market made by a joint-stock company incorporated domestically, and the latter refers to securities offering and listing in an overseas market made in the name of an offshore entity, while based on the underlying equity, assets, earnings or other similar rights of a domestic company which operates its main business domestically. According to the Trial Measures, if an issuer meets the following conditions, the offering and listing shall be determined as an indirect overseas offering and listing by a domestic company: (i) the total assets, net assets, revenues or gross profits of the domestic company(ies) of the issuer in the most recent financial year account for more than 50% of the corresponding figure in the issuer's audited consolidated financial statements over the same period; (ii) the majority of the senior management in charge of business operation and management of the issuer are Chinese citizens or habitually reside in China, or its main places of business operation are located in China or main parts of its business activities are conducted in China.

Under the Trial Measures and supporting guidelines, a filing-based regulatory system **would be** **was** implemented covering both direct and indirect overseas offering and listing. For an indirect initial public offering and listing in an overseas market, the issuer shall designate a major domestic operating entity to submit the filing documents to the CSRC, including but not limited to the prospectus within three working days after such application of overseas offering and listing is submitted. The CSRC would, within 20 working days if filing documents are complete and in compliance with the stipulated requirements, complete the filing and publish the filing information on the CSRC's official website. While for confidential filings of overseas offering and listing application documents, the designated filing entity may apply for an extension of the publication of such filing. The issuer shall report to the CSRC within three working days after the overseas offering and listing application documents become public. In addition, subsequent securities offerings of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three working days after the offering is completed.

66

[Table of Contents](#)

Meanwhile, overseas offering and listing would be prohibited under certain circumstances, including but not limited to that (i) the offering and listing are expressly forbidden by the Chinese laws, regulations and relevant rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws or (iii) there are material disputes with regard to the ownership of the equity held by the domestic company's controlling shareholder or by other shareholders that are controlled by the controlling shareholder and/or actual controller. If a domestic company falls into the circumstances where overseas offering and listing is prohibited prior to the overseas offering and listing, the domestic company shall postpone or terminate the intended overseas offering and listing, and report to the CSRC and competent authorities under the State Council in a timely manner.

If domestic companies fail to fulfill the above-mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they would be warned and fined up to RMB 10 million. The controlling shareholders and actual controllers of such domestic companies that organize or instruct the

65

[Table of Contents](#)

aforementioned violations would be fined up to RMB10 million and directly liable persons-in-charge and other directly liable persons would be each fined up to RMB 5 million. [Other Chinese National- and Provincial-Level Laws and Regulations.](#)

Other Chinese National- and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

Employees and Human Capital Resources

As of [December 31, 2022](#) [December 31, 2023](#), we had [6893](#) full-time employees, [3035](#) of whom have a Ph.D. or M.D. Of these [6893](#) employees, [4566](#) were engaged in research and development activities and [2327](#) were engaged in business development, finance, information systems, facilities, human resources or administrative support. [Five](#) [Four](#) of the non-research and development-based employees were based in Shanghai, China [and one based in the UK](#), while the other [1822](#) resided in the United States. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

We are a Cayman Islands exempted company incorporated with limited liability. We were initially formed as a Delaware corporation in 2016 under the name ShouTi Inc., and reorganized as a Cayman Islands exempted company in 2019. We completed our IPO on February 7, 2023, and our ADS began trading on the Nasdaq Global Market on February 3, 2023.

Our principal executive office is located at [611](#) [601](#) Gateway Blvd., Suite [223](#), [900](#), South San Francisco, California 94080 and our telephone number is (628) 229-9277. The principal executive office of our research and development operations is located at Unit [02](#), [F5](#), No. [1](#), [01](#), [11th](#) floor, Lane 2889, Jinke Road, [China \(Shanghai\) Free Trade Zone](#), [Pudong New Area](#), Shanghai, People's Republic of China, 201203. Our telephone number at this address is 86 21 61215839. Our current registered office in the Cayman Islands is located at the offices of International

[67](#)

[Table of Contents](#)

Corporation Services Ltd., P.O. Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

Our website is www.structuretx.com. Information contained on, or accessible through, our website shall not be deemed incorporated into, and is not a part of, this Annual Report. We have included our website in this Annual Report solely as an inactive textual reference.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act are available on our website, free of charge, as soon as reasonably practicable after the reports are electronically filed or furnished to the Securities and Exchange Commission, or SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information that we file with the SEC electronically.

[Table of Contents](#)
Item 1A. Risk Factors.

Investing in our ADS securities 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 Annual Report, including our consolidated financial statements and their related notes included elsewhere in this Annual Report and Part II. Item 7. "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, GSK-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

[Table of Contents](#)

continue to incur significant and increasing operating losses for at least the next several years. Our net losses were \$51.3 million \$89.6 million and \$38.0 million \$51.3 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of \$117.0 million \$206.6 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

67

[Table of Contents](#)

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 GSK-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 have and expect to continue 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 December 31, 2022, together with the net proceeds of \$166.7 million from our Initial Public Offering, or IPO, in February 2023, December 31, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements through at least 2025, 2026. 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 the COVID-19 pandemic and actions taken to slow its spread, as well as actual or anticipated changes in interest

69

[Table of Contents](#)

rates and economic inflation and the impact of the **Russian/Russia/Ukraine conflict and Israel-Hamas war**, 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 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;

68

[Table of Contents](#)

- 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; and**
- **costs associated with any delays or issues caused by the ongoing COVID-19 pandemic; 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. **For example, in October 2023, we issued and sold an aggregate of 21,617,295 ordinary shares and 2,401,920 newly designated non-voting ordinary shares in the Private Placement.** 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

70

[Table of Contents](#)

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,

69

[Table of Contents](#)

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, GSK-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, GSK-1290 and ANPA-0073, in early clinical development. We completed a Phase 1 SAD study of GSK-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 otherwise healthy overweight subjects in March 2023. We plan to submit a protocol amendment to also initiated the FDA to transition to a dosing of the Phase 2a proof-of-concept study in May 2023. We reported topline data for the 28-day Phase 1b MAD study in September 2023, in which GSK-1290 was generally well-tolerated with no adverse event-related discontinuations and demonstrated an encouraging safety profile and significant weight loss up to 4.9% placebo-adjusted, supporting once-daily dosing. We also reported topline data for the 12-week Phase 2a clinical trial in December 2023, in which GSK-1290 was generally well-tolerated with no treatment-related SAEs, no AE-related discontinuation in obesity and only one adverse event-related discontinuation in T2DM. Furthermore, GSK-1290 demonstrated significant reductions in HbA1c and weight at 12 weeks in T2DM. We further reported interim Phase 2a obesity cohort data, in which GSK-1290 demonstrated significant reductions in weight at 8 weeks. We expect to report the full 12-week obesity data in the latter half of the second quarter of 2024. We also reported results from a Japanese ethno-bridging study and findings from 6- and 9-month toxicology studies demonstrating encouraging safety to support advancing into Phase 2b development. The additional formulation bridging study to evaluate a tablet formulation of GSK-1290 is expected to be completed in the latter half of the second quarter of 2024. Pending supportive data from this bridging study, the tablet formulation would be used in future GSK-1290 studies starting with the Phase 2b study for obesity and an additional Phase 2 study for T2DM, and obesity with expected initiation which we

expect to initiate both in the second half of 2023, 2024. Additionally, we completed our Phase 1 SAD and MAD study for ANPA-0073 in healthy volunteers for IPF and PAH in September 2022. We expect to conduct additional preclinical studies of ANPA-0073 for its effects in selective weight loss. 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;

71

[Table of Contents](#)

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

70

[Table of Contents](#)

- 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 **NHPs 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, due in part to an increase in demand from companies and other institutions developing vaccines and treatments for COVID-19 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. For example, in December 2023, we reported topline data from our 12-week Phase 2a clinical trial, which focused on safety and tolerability of GSK-1290 in a total of 94 participants to date, including 60 participants randomized to GSK-1290. The results showed GSK-1290 was generally well-tolerated with no treatment-related SAEs, no adverse event-related discontinuation in obesity and only one adverse event-related discontinuation in T2DM. Furthermore, GSK-1290 demonstrated

71

[Table of Contents](#)

significant reductions in hemoglobin A1c and weight at 12 weeks in T2DM. We further reported interim Phase 2a obesity cohort data, in which GSK-1290 demonstrated significant reduction in weight at 8 weeks. Due to the preliminary nature of these results and the length of the study and sample size, these results are not necessarily indicative of the final results for our clinical trials for GSK-1290. 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

72

[Table of Contents](#)

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 GSK-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 GSK-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 GSK-1290, the FDA may disagree or take action which could delay our GSK-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. For example, in September 2023 we reported that a data collection omission had occurred at a clinical site that impacted the obesity cohort (120 mg dose level) of the Phase 2a study for GSB-1290, where weight was not collected at the final (week 12) visit for 24 of the 40 enrolled participants. Other safety and laboratory assessments were measured at all visits, including the week 12 visit as per protocol. We have completed the enrollment of additional participants in the Phase 2a obesity cohort to replace those for whom 12-week weight data was not collected. The replacement participants will follow the same study protocol, without changes in the titration schema or target dose (120 mg at once-daily dosing). However, as a result of this data collection omission, we reported interim Phase 2a obesity cohort data in December 2023, and we expect to report the full 12-week obesity data in the latter half of the second quarter of 2024.

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;

72

[Table of Contents](#)

- 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 IRBs 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 such as the data collection omission we experienced at a clinical site as discussed above or dropping out of a trial;

73

[Table of Contents](#)

- 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 AEs or 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.

73

[Table of Contents](#)

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. In addition, although the pandemic has waned, any disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter difficulties or delays in initiating, screening, enrolling, conducting, or completing our ongoing and planned preclinical studies and clinical trials. Clinical site initiation and patient screening and enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. 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 who, as healthcare providers, may have heightened exposure to COVID-19, could be limited, which in turn could adversely impact our clinical trial operations.

74

[Table of Contents](#)

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 the ongoing COVID-19 pandemic. As a result of the COVID-19 pandemic, we public health concerns. We have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. To date, we have 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. consumables and due to the data collection omission at a clinical site as discussed above. These delays

have not resulted in a material impact on our operations; however, such 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

74

[Table of Contents](#)

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;

75

[Table of Contents](#)

- 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. **If we encounter any delays in enrolling such additional participants, this may further delay our clinical trial.** 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 **such as the ongoing COVID-19 pandemic,** 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, **whether as a result of the COVID-19 pandemic and related illness or actions taken to slow the spread of COVID-19 or otherwise,** 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

75

[Table of Contents](#)

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

76

[Table of Contents](#)

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 and Phase 1b MAD 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 2a study of GSBR-1290, the following adverse events occurred and were considered probably or possibly related to the study drug: nausea, headache, vomiting, decreased appetite, dyspepsia, 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;

76

[Table of Contents](#)

- 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.

77

[Table of Contents](#)

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 GSB-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 GSB-1290 in healthy volunteers in September 2022. We reported topline data for the Phase 1b MAD study in September 2023. We also reported topline data for the 12-week Phase 2a clinical trial in December 2023. We further reported interim Phase 2a obesity cohort data, in which GSB-1290 demonstrated significant reductions in weight at 8 weeks. We expect to report the full 12-week obesity data in the latter half of the second quarter of 2024. We also reported results from a Japanese ethno-bridging study and findings from 6- and 9-month toxicology studies demonstrating encouraging safety to support advancing into Phase 2b development. The additional formulation bridging study to evaluate a tablet formulation of GSB-1290 is expected to be completed in the latter half of the second quarter of 2024. Additionally, we completed our Phase 1 SAD and MAD study for ANPA-0073 in healthy volunteers for IPF and PAH in September 2022. 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

[Table of Contents](#)

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.

78

[Table of Contents](#)

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.

78

[Table of Contents](#)

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.

79

[Table of Contents](#) 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

79

[Table of Contents](#)

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 GSB-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 GSB-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 GCP 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

80

[Table of Contents](#)

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.

80

[Table of Contents](#)

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. For example, in December 2023, we reported clinically meaningful topline data from our 12-week Phase 2a clinical trial, which focused on safety and tolerability of GSK-1290 in a total of 94 participants to date, including 60 participants randomized to GSK-1290. The results showed GSK-1290 was generally well-tolerated with no treatment-related SAEs, no adverse event-related discontinuation in obesity and only one adverse event-related discontinuation in T2DM. Furthermore, GSK-1290 demonstrated significant reductions in HbA1c and weight at 12 weeks in T2DM. We further reported interim Phase 2a obesity cohort data, in which GSK-1290 demonstrated significant reductions in weight at 8 weeks. Due to the preliminary nature of these results and the length of the study and sample size, these results are not necessarily indicative of the final results for our clinical trials for GSK-1290. If the final data is materially different from the preliminary topline data reported, this 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

81

[Table of Contents](#)

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.

81

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.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA postponed most inspections of domestic and foreign manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site

inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, in April 2021, the FDA began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities, in circumstances where the FDA determines that such remote evaluation would be appropriate, based on mission needs and travel limitations. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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. However, certain Chinese biotechnology companies and CMOs may become subject to trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to

82

[Table of Contents](#)

us. We have contracted with, or are in the process of pursuing contracts with, alternative suppliers or manufacturers outside of China for our active pharmaceutical ingredients and drug product for our product candidates. While we believe that adequate our current manufacturing plan will provide us with alternative sources for such supplies, exist, there is a risk that, if supplies are interrupted, or the quality of ingredients provided by such alternative sources is not to our specification, it would cause delays in our supply chain and increase the cost of manufacturing our drugs, which could 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.

83

[Table of Contents](#)

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 the COVID-19 pandemic, 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, 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 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.

83

[Table of Contents](#)

Our or a **third-party's 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.

84

[Table of Contents](#)

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** We have experienced delays due to actions of third parties in the past and if in the future 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

84

[Table of Contents](#)

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. *For example, in September 2023 we announced that topline data from the obesity cohort of our Phase 2a trial of GSK-1290 would be delayed because of a data collection omission by a clinical site, where weight was not collected at the final (week 12) visit for 24 of the 40 enrolled participants. We expect to report the full 12-week obesity data in the latter half of the second quarter of 2024.* Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of participants *or ensure the collection of requisite data by clinical sites*, we may be required to *enroll additional participants or* 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, *related to COVID-19 or other infectious diseases could impact personnel at our CROs*, 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

85

[Table of Contents](#)

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.

[Table of Contents](#)

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;

86

[Table of Contents](#)

- 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

86

[Table of Contents](#)

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 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 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

87

[Table of Contents](#)

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.

87

[Table of Contents](#)

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

In October 2020, Lhotse, our wholly-owned subsidiary, entered into the Lhotse-Schrödinger Agreement. In November 2023, Aconcagua, our wholly-owned subsidiary, entered into the Aconcagua-Schrödinger Agreement. Under the Lhotse-Schrödinger Agreement, both agreements, 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, both agreements. See the discussion in Part I. Item 1. "Business—Lhotse Collaboration Agreement with Schrödinger, LLC, dinger" and Part I. Item 1. "Business—Aconcagua Collaboration Agreement with Schrödinger."

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 or Aconcagua-Schrödinger Agreement, disagrees with our interpretation of the terms of the collaboration collaborations or our discovery plan or terminates the Lhotse-Schrödinger Agreement or Aconcagua-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, Agreement or Aconcagua-Schrödinger

Agreement, as applicable. If either of our collaboration collaborations 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

88

[Table of Contents](#)

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.

88

[Table of Contents](#)

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, 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

[Table of Contents](#)

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;

90

[Table of Contents](#)

- 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

[Table of Contents](#)

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;

[Table of Contents](#)

- 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

91

[Table of Contents](#)

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.

92

[Table of Contents](#)

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

92

[Table of Contents](#)

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, Altimune, Inc., Carmot Therapeutics, Inc. (which was acquired by Roche Group in January 2024), 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, which was recently acquired by Amgen, 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

93

[Table of Contents](#)

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.

93

[Table of Contents](#)

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

94

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;

94

- 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

95

[Table of Contents](#)

- 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.

95

[Table of Contents](#)

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 **December 31, 2022** **December 31, 2023**, we had **68** **93** 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;

96

[Table of Contents](#)

- 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.

Our business and the business or operations of third parties with whom we conduct business has been and could continue to be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have business operations.

Our business has been and could continue to be adversely affected by the global COVID-19 pandemic. In response to the COVID-19 pandemic, we implemented and continue to enhance safety measures in all our facilities, which may negatively impact our business and our preclinical and clinical programs. As public health directives surrounding the pandemic have relaxed, we have modified our safety measures, taking into consideration government restrictions, employee safety, and health risks. Our approach may vary among geographies depending on appropriate health protocols, and may change at any time in response to changes in the COVID-19 pandemic. The status of global economic recovery remains uncertain and unpredictable.

[Table of Contents](#)

and we will continue to be impacted by developments in the pandemic including any subsequent waves of outbreak or new variant strains of COVID-19 which may require re-closures or other preventative measures. The COVID-19 pandemic may also have long-term effects on the nature of the office environment and remote working, which may present risks for our strategy, operational, talent recruiting and retention, and workplace culture. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

As a result of the COVID-19 pandemic, we may experience, or continue to experience, ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical trial endpoints;
- interruption or delays in the operations of the FDA or applicable foreign authorities, which may impact review and approval timelines;
- interruption or delays in our operations due to staffing shortages, travel restrictions, quarantines, production slowdowns or stoppages and disruptions in delivery systems;

- the need for additional manufacturing space, facilities upgrades and personnel;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- inability or unwillingness of some patients to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- interruptions in our preclinical studies and clinical trials due to restricted or limited operations at our laboratory facilities;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruptions or delays to our discovery and clinical activities.

COVID-19 and actions taken to reduce its spread continue to evolve. The extent to which the COVID-19 pandemic impacts our business, our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, emergence and spread of variants, travel restrictions, quarantines, social distancing requirements and business closures in the United States and internationally, and business disruptions, and the effectiveness of actions taken in the United States and internationally to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. To date, we have experienced

[Table of Contents](#)

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. Such delays have previously impacted and could in the future adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic or any future epidemic disease adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

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 other healthcare providers, 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

97

[Table of Contents](#)

states and other jurisdictions in which we may conduct our business. The laws that **will 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;

98

[Table of Contents](#)

- 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 **HIPAA**, **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 **HITECH**, **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 Centers for Medicare & Medicaid Services \("CMS"\)](#) 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

98

[Table of Contents](#)

- 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

99

[Table of Contents](#)

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. **It is unclear how other health reform measures of the Biden administration will impact our business.**

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

99

[Table of Contents](#)

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 **HHS 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 they may 2023.** On August 29, 2023, HHS announced the list of the first ten drugs that **will** be subject to price negotiations, 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. **Further, In addition, in response to the Biden administration released an additional administration's October 2022 executive order, on October 14, 2022 February 14, 2023, directing HHS to released a report on how 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. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can **be further leveraged** use when deciding to **test** exercise march-in rights. While march-in rights have not previously been exercised, **it is uncertain if that will continue under the new models for lowering drug costs for Medicare and Medicaid beneficiaries.** framework.

Individual states in the United States have also become increasingly active in passing legislation and

100

[Table of Contents](#)

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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. 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

100

[Table of Contents](#)

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;

101

[Table of Contents](#)

- 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 result in significant financial, legal, regulatory, business and reputational harm to us resulting from harm; litigation; fines and penalties; disruptions of our business operations; reputational harm; 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

101

[Table of Contents](#)

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 COVID-19 pandemic, we have enabled all of our employees to work remotely, which may make us more vulnerable to cyberattacks. Cyber incidents 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

102

[Table of Contents](#)

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.

102

[Table of Contents](#)

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.

103

[Table of Contents](#)

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 health and data protection laws and regulations such obligations could lead to government enforcement actions, which could include civil, criminal or administrative penalties, private litigation (including class claims) and arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, adverse publicity, and/or and other adverse publicity business consequences and could negatively affect our operating results and business, financial condition, results of operations and prospects.

103

[Table of Contents](#)

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we may collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information.

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. In the United States, 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.

In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services.

Certain states have also adopted comparable impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy and security impact assessments. These state laws and regulations governing the privacy, processing and protection of personal information allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CCPA" CPRA), (collectively, "CCPA") applies to personal information data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents such individuals to exercise certain privacy rights. The CCPA provides for civil penalties fines of up to \$7,500 per intentional 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. Other states, such as Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws, and similar Similar laws are being considered in several other states, as well as at the federal and local levels. levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some

[Table of Contents](#)

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. For example, the CCPA took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and places increased privacy and security obligations on organizations that handle certain personal information of consumers or households. The CCPA requires covered companies to provide disclosures to consumers about such companies' data collection, use and sharing practices, provide such consumers with data privacy rights such as rights to access and delete their personal information, receive detailed information about how their personal information is used, and opt-out of certain sharing of personal information. 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 passed in California. The CPRA significantly amends the CCPA and will impose 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 will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions came into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Further, Virginia enacted the Virginia Consumer Data Protection Act ("VCDPA") effective January 1, 2023, Colorado passed the Colorado Privacy Rights Act ("CPA") effective July 1, 2023, Connecticut passed the Connecticut Data Privacy Act ("CDPA")

effective July 1, 2023, and Utah passed the Utah Consumer Privacy Act ("UCPA"), effective December 31, 2023. A number of other proposals exist for new federal and state privacy legislation that could increase our potential liability, increase our compliance costs, and affect our ability to collect personal information. The VCDPA, CPA, CDPA and UCPA are similar to the CCPA and CPRA but aspects of these 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 such 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.

104

[Table of Contents](#)

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. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. 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 EEA European Economic Area ("EEA") and UK 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

105

[Table of Contents](#)

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.

105

[Table of Contents](#)

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.

106

[Table of Contents](#)

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.

106

[Table of Contents](#)

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.

107

[Table of Contents](#)

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. Outside the U.S., various governments and organizations are increasingly focused on tax reform and other legislative or regulatory action to increase tax revenue, including the Organisation for Economic Co-operation and Development's Base Erosion and Profit Shifting Project ("BEPS 2.0"). The IRA, TCJA, BEPS 2.0 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. The Chinese government may intervene in or influence our operations, which could result in a change in our operations and impact the value of our ADSs. Any economic downturn, whether actual or perceived, further decrease in economic growth rates or an otherwise uncertain economic outlook could affect our business, financial condition and results of operations, as well as the market price of our ADSs. In addition, the global macroeconomic environment is facing challenges. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions, and our business operations in the long term. 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

107

[Table of Contents](#)

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 Chinese government may intervene with our operations and United States increase, our business in China and United States, as well as the market price of our ADSs, may also be affected.

[Table of Contents](#)

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 new rules published for comments by the Chinese government, including the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) published on December 24, 2021, 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 variable interest entity ("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 CSRC 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 or 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 SCNPC 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 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 Cyberspace Administration of China ("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

110

[Table of Contents](#)

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 Annual 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

109

[Table of Contents](#)

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 **to be** set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the Personal Information Protection Law contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China.

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

111

[Table of Contents](#)

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, and the Biosecurity Law of the PRC. PRC and the HGR Implementing Rules.

110

[Table of Contents](#)

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 **will come 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

112

[Table of Contents](#)

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."

As of the date of this Annual 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 **come came** into effect on March 31, 2023, we **will would** 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 **which are determined as indirect overseas offering and listing by a domestic company under the Trial Measures,** we

111

[Table of Contents](#)

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 subsequent securities to foreign investors, offering in the same overseas market,** 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.

113

[Table of Contents](#)

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;

112

[Table of Contents](#)

- 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

114

[Table of Contents](#)

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

113

[Table of Contents](#)

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. **Development 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 PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. As the laws and regulations are relatively new and the PRC legal system continues to evolve, there may be room for discretion in the implementation of these laws and regulations. And as these laws and regulations are evolving in response to changing economic and other conditions, factors related to the application and 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.

115

[Table of Contents](#)

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 114

[Table of Contents](#)

Regulatory Requirements 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 certain foreign exchange controls regulations and, in the case of transactions under the capital account, requires the approval of and/or registration with Chinese government authorities, including the SAFE, 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 MOFCOM, Ministry of Commerce of the People's Republic of China ("MOFCOM"), or its local branch or registration with other governmental authorities in China.

116

[Table of Contents](#)

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 receive 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

115

[Table of Contents](#)

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.

117

[Table of Contents](#)

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

116

[Table of Contents](#)

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

118

[Table of Contents](#)

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 \(the "Stock Option Rules, Rules"\)](#). In accordance with the Stock Option Rules and other relevant

117

[Table of Contents](#)

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

119

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 the COVID-19 pandemic 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

120

[Table of Contents](#)

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

119

[Table of Contents](#)

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

121

[Table of Contents](#)

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

120

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, (including as a result of COVID-19 impacting our operations), 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

[Table of Contents](#)

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

[Table of Contents](#)

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

122

[Table of Contents](#)

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.

124

[Table of Contents](#)

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

123

[Table of Contents](#)

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 **including due to the effect of the COVID-19 pandemic on us, our licensors or our vendors,** 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

125

[Table of Contents](#)

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 GSK-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.

124

[Table of Contents](#)

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;

126

[Table of Contents](#)

- 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.

125

[Table of Contents](#)

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

127

[Table of Contents](#)

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.

126

[Table of Contents](#)

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

128

[Table of Contents](#)

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

127

[Table of Contents](#)

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

129

[Table of Contents](#)

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** **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.

128

[Table of Contents](#)

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

130

[Table of Contents](#)

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 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

129

[Table of Contents](#)

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.

131

[Table of Contents](#)

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,

130

[Table of Contents](#)

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.

132

[Table of Contents](#)

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 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

131

[Table of Contents](#)

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.

133

[Table of Contents](#)

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

132

[Table of Contents](#)

addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual 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;

134

[Table of Contents](#)

- 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;

133

[Table of Contents](#)

- 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;

135

[Table of Contents](#)

- general political, geopolitical and economic macroeconomic conditions, including as a result of bank failures, global pandemics, the COVID 19 pandemic, Russia/Ukraine conflict or the Russia/Ukraine conflict, Israel-Hamas war; 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 the audit report included in this Annual Report is prepared by 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

134

[Table of Contents](#)

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.

136

[Table of Contents](#)

We have retained 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, reporting in the past, one of which has not been remediated and continues to exist as of December 31, 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

The material weaknesses are weakness which continues to exist as follows:

We of December 31, 2023 is that 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, objectives.

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. However, these This material weaknesses weakness could result in a misstatement of substantially all of our accounts or disclosures that

137 135

[Table of Contents](#)

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 weakness 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 weakness as efficiently and effectively as possible and full remediation may go beyond December 31, 2023. possible. 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, weakness, the implementation of these measures may not fully address the material weaknesses weakness and deficiencies deficiency 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 weakness 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 II, Item 9A. "Controls and Procedures— Management's Plan to Remediate the Material Weakness".

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 March 15, 2023 December 31, 2023, our executive officers, directors, five percent shareholders and their affiliates beneficially owned approximately 54% 34% 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.

As of December 31, 2022, 77,544,741 ordinary shares will be (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) become available for sale in the public market, beginning on August 1, 2023, following the expiration of lock-up agreements entered into by substantially all of our shareholders in connection with the IPO. Jefferies LLC and SVB Securities LLC may agree to release these shareholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of ordinary shares (through ADSs) in the public market. Sales of a substantial number of such shares, upon expiration of the lock-up agreements, or 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 October 2023, we completed our Private Placement for aggregate gross proceeds of approximately \$300 million before deducting placement agent fees and other private placement expenses. An aggregate of

138 136

[Table of Contents](#)

21,617,295 ordinary shares and 2,401,920 newly designated non-voting ordinary shares were issued pursuant to the Purchase Agreement. Each holder of the non-voting ordinary shares had the right to convert each non-voting ordinary share held by such holder into one ordinary share, subject to certain beneficial ownership limitations, as described further in the description of the rights of the non-voting ordinary shares included as Exhibit 4.5 to this Annual Report. The purchase price was \$12.49 per share (or the equivalent of \$37.47 per ADS), which represents the ADS closing price on the Nasdaq Global Market immediately preceding the signing of the Purchase Agreement on September 29, 2023. As of December 31, 2023, all outstanding non-voting ordinary shares had been converted into ordinary shares.

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 the lock-up agreements described above 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, 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

137

[Table of Contents](#)

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

139

[Table of Contents](#)

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

138

[Table of Contents](#)

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

140

[Table of Contents](#)

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 Annual 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 net operating loss carryforwards and certain other tax attributes may be limited.

As of **December 31, 2022** December 31, 2023, we had **\$66.4 million** **\$84.8 million** and **\$146.5 million** of U.S. federal NOLs and **\$74.6 million** of state NOLs net operating loss ("NOL") carryforwards, respectively, available to offset future taxable income. Under U.S. federal NOL carryforwards totaling **\$66.4 million** can income tax law, federal NOLs incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, under current law. State NOL carryforwards totaling **\$74.6 million** but the deductibility of such federal NOLs is limited to 80% of taxable income for taxable years beginning after December 31, 2020. Any NOLs incurred in tax years beginning before December 31, 2017, may be used to offset up to 100% of future taxable income, but will begin to expire in varying amounts in 2037, unless previously utilized. Similar rules may apply under state tax laws. As of **December 31, 2022** December 31, 2023, we also had aggregate U.S. federal and state R&D credits of approximately **\$0.6 million** **\$2.2 million** and **\$0.3 million** **\$0.5 million**, respectively. U.S. federal R&D credits carryforwards begin to expire in **2029** **2039** 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

139

[Table of Contents](#)

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.

141

[Table of Contents](#)

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** **Annual Report** on Form 10-K for the **fiscal** 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, as discussed below**, 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**", **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

140

[Table of Contents](#)

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

142

[Table of Contents](#)

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.

143 141

[Table of Contents](#)

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 Annual Report, our board of directors will have the authority to issue up to 100,000,000 90,187,562 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

144 142

[Table of Contents](#)

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 our fiscal 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. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company.

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.

143

[Table of Contents](#)

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

145

[Table of Contents](#)

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 fiscal year ending December 31, 2023, we will be are 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 has in the past and may in the future identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. For example, we have identified material weaknesses in our internal control over financial reporting in the past, one of which has not been remediated and continues to exist as of December 31, 2023. 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 if we are unable to maintain remediate our material weakness and conclude that our internal control over financial reporting is effective, or if in the future our independent registered public accounting firm determines we have a material weakness in our internal controls control over financial reporting, this 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.

144

[Table of Contents](#)

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.

146

[Table of Contents](#)

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 II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements."

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, litigation or material legal proceedings which could have a negative impact on our reputation or business.

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. In addition, from time to time, we have been and may in the future be involved in legal and regulatory proceedings or investigations concerning matters that arise in the ordinary course of our business. Such proceedings could result in significant fines or penalties, have an adverse impact on our reputation, business and financial condition or results or operations and divert the attention of our management from the operation of 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

145

[Table of Contents](#)

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

147

[Table of Contents](#)

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.

148 146

[Table of Contents](#)

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and trade secrets, data we may collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information ("Information Systems and Data").

The cybersecurity function within the Company helps identify, assess and manage the Company's cybersecurity threats and risks. Our cybersecurity function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example manual tools, internal or external audits, automated tools, subscribing to and analyzing reports and services that identify cybersecurity threats and threat actors, conducting vulnerability assessments to identify vulnerabilities, conducting scans of the threat environment, and evaluating threats reported to us. Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response policy, incident detection and response, data encryption, network security controls, system monitoring, penetration testing, employee training, a dedicated cybersecurity staff member, and physical security mechanisms.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, the cybersecurity function works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity software providers, managed cybersecurity service providers, and penetration testing firms. We also use third-party service providers to perform a variety of functions throughout our business, such as application providers and hosting companies. We manage cybersecurity risks associated with our use of these providers by reviewing their security assessments and applicable reports.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including:

- Confidentiality agreements with employees and third-parties may not prevent unauthorized disclosure of trade secrets and other proprietary information;
- The adoption and deployment of AI in our, and any third-party collaborators' operations, and in particular our and any third-party collaborators' R&D efforts to explore new targets and develop effective products, may not be effective and may expose us to risk;
- 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;

147

[Table of Contents](#)

disruptions of our business operations; loss of revenue or profits; loss of customers or sales; or other adverse consequences; and

- 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.

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. Our Audit Committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Senior Director of Internal Controls and SOX Compliance, who has over 20 years in the areas of internal controls and SOX compliance

reporting; our Director of IT Security and Compliance, who has over 20 years of IT experience, the past four of which have been in security; and our CFO, who has over 20 years of business development experience.

Our cybersecurity function is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Our CFO and cybersecurity function are responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our response process to cybersecurity incidents is designed to escalate certain incidents to members of management depending on the circumstances, including the CFO. Our CFO and others work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response policy includes reporting to the Audit Committee for certain cybersecurity incidents.

The Audit Committee receives periodic reports from our cybersecurity function concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The Audit Committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation. We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition..

Item 2. Properties.

Our principal executive office is located in South San Francisco, California where we lease a total of approximately 50011,800 square feet of office space that we use for our administrative and other activities. The lease for this office space renews automatically at the end of each calendar month, unless or until we provide notice of our intent not to renew the lease. We entered into a new sublease agreement to rent approximately 4,100 square feet of office space commenced in South San Francisco, California, which lease expires in October 2023. July 2023 and will expire on August 31, 2027. We also have a development and operations office located in Shanghai, China where we lease a total of approximately 5,90022,500 square feet of office space. This lease expires on September 15, 2023, December 31, 2026. We also lease a total of approximately 8,400 square feet of laboratory space located in Shanghai, China for our research and we may request to renew it. development activities. This lease expires on January 31, 2027. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. 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 have been and may in the future be involved in legal and regulatory proceedings or investigations concerning matters that arise in the ordinary course of

148

[Table of Contents](#)

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 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our ADSs have been listed on the Nasdaq Global Market under the symbol "GPCR" since February 3, 2023. Prior to this date, there was no public market for our ADSs.

Holders of Ordinary Shares

As of **March 15, 2023** **February 29, 2024** there were **63 25** holders of record of our ordinary shares. The actual number of **shareholders** **beneficial owners of ordinary shares** is greater than this number of record holders and includes **shareholders** **persons** who are beneficial owners but whose shares are held in street name by brokers and other nominees. JPMorgan Chase Bank, N.A. is the depositary for our ADSs.

Dividend Policy

149

[Table of Contents](#)

We have never declared or paid dividends on our ordinary shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration, amount and payment of any dividends in the future will be determined by our board of directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual, legal, tax and regulatory restrictions. **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.** If we elect to pay such dividends in the future, we may reduce or discontinue entirely the payment of such dividends at any time. If we pay any dividends, ADS holders will generally have the right to receive the dividends paid on the underlying ordinary shares, subject to the terms of the deposit agreement by and among us, the depositary and the holders and beneficial owners of ADSs, including the fees and expenses payable thereunder.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference to Part III, Item 12 of this Annual Report on Form 10-K.

Unregistered Sales of Equity Securities

In April 2022, On September 29, 2023, we entered into the Purchase Agreement with certain institutional investors (the "Purchasers"), pursuant to which we issued and sold to the Purchasers an aggregate of 8,155,272 Series B redeemable convertible preferred 21,617,295 ordinary shares \$0.0001 par value ("Series B preferred shares"), for an aggregate consideration and 2,401,920 newly designated non-voting ordinary shares. The Private Placement closed on October 3, 2023. Each holder of \$33.0 million non-voting ordinary shares had the right to convert each non-voting ordinary share held by such holder into one ordinary share, subject to certain investors. The offers, sales and issuances beneficial ownership limitations, as described further in the description of the Series B preferred rights of the non-voting ordinary shares included as Exhibit 4.5 to this Annual Report. The purchase price is \$12.49 per Share (or the equivalent of \$37.47 per ADS), which represents the ADS closing price on the Nasdaq Global Market immediately preceding the signing of the Purchase Agreement, for aggregate gross proceeds of approximately \$300 million before deducting placement agent fees and offering expenses. During the fourth quarter of 2023, all outstanding non-voting ordinary shares converted into ordinary shares.

149

[Table of Contents](#)

The shares were deemed issued to be exempt the Purchasers in reliance upon the exemption from the registration under requirements of the Securities Act in reliance on provided by Section 4(a)(2) (or were deemed to be exempt from registration under the Securities Act in reliance on

Section 4(a)(2) or Regulation D promulgated thereunder) in that the issuance of securities to the accredited investors did thereof, as a transaction by an issuer not involve involving a public offering. The recipients of We relied on this exemption from registration based in part on representations made by the Series B preferred Purchasers in the Purchase Agreement that the shares were each an accredited investor under Rule 501 of Regulation D and have been acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof.

Jefferies LLC and Leerink Partners LLC acted as joint placement agents for the Private Placement. Each issued and outstanding Series B preferred share was automatically converted into one ordinary share upon the closing received a portion of our IPO on February 7, 2023.

During the year ended December 31, 2022, we granted options a combined fee equal to purchase an aggregate of 4,218,372 ordinary shares to employees, senior management, non-employee directors and consultants at exercise prices ranging from \$2.60 to \$3.36 per share under our 2019 Equity Incentive Plan, as amended.

The offers, sales and issuances 6.0% of the options were deemed to be exempt from registration under aggregate gross proceeds, plus the Securities Act in reliance on either Rule 701, in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or Section 4(a)(2), for transactions by an issuer not involving a public offering, reimbursement of certain expenses.

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.

150

[Table of Contents](#)

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).

Purchases of Equity Securities by the Issuer

None.

Taxation

The following is a discussion of the material Cayman Islands, PRC and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our ADSs or ordinary shares. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decisions to acquire ADSs or ordinary shares.

Material Cayman Islands Taxation

Regardless of the application of Section 7874 of the Code (as discussed below), we are also treated as a Cayman Islands corporation for Cayman Islands tax purposes. However, we are not subject to income or capital gains tax under the current laws of the Cayman Islands. We believe there are no other taxes likely to be material to us levied by the government of the Cayman Islands. We are and are expected to

continue to be a Cayman Islands corporation as of the date of this Annual Report. We are treated as an exempted company for Cayman Islands tax purposes.

Material PRC Taxation

We are a holding company incorporated in the Cayman Islands.

Under the EIT Law and its implementation rules, an enterprise established outside of China with a “de facto management body” within China is considered a “resident enterprise,” and will be subject to the enterprise

150

Table of Contents

income tax on its global income at the rate of 25%. The implementation rules define the term “de facto management body” as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the SAT issued SAT Circular 82, which provides certain specific criteria for determining whether the “de facto management body” of a Chinese-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by Chinese enterprises or Chinese enterprise groups, not those controlled by Chinese individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation’s general position on how the “de facto management body” text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, all offshore enterprises controlled by a Chinese enterprise or a Chinese enterprise will be regarded as a Chinese tax resident by virtue of having its “de facto management body” in China only if all of the following conditions are met:

- (i) the primary location of the day-to-day operational management is in China;
- (ii) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in China;
- (iii) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and
- (iv) at least 50% of voting board members or senior executives habitually reside in China.

We believe that neither we nor any of its subsidiaries outside of China is a Chinese resident enterprise for Chinese tax purposes. We are not controlled by a Chinese enterprise or Chinese enterprise group, and we do not believe that we meet all of the conditions above. We are a company incorporated outside China. As a

151

Table of Contents

holding company, a majority of assets are located, and our records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside China. For the same reasons, we believe our other subsidiaries outside of China are also not Chinese resident enterprises 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 are a Chinese resident enterprise for Enterprise Income Tax (“EIT”), purposes, we may be required to withhold tax at a rate of 10% on dividends we pay to our shareholders, including holders of our ADSs, that are non-resident enterprises. In addition, 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 ordinary shares or ADSs, 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-Chinese 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 Chinese resident enterprise. If any Chinese tax were to apply to dividends realized by non-Chinese individuals, it will generally apply at a rate of 20%. The Chinese tax liability may be reduced under applicable tax treaties. However, it is unclear whether our non-Chinese shareholders would be able to claim the benefits of any tax treaty between their country of tax residence and China in the event that we are treated as a Chinese resident enterprise.

See Part I, Item 1A. "Risk Factors ■ Risks Related to Doing Business in China and Our International Operations-If we are classified as a China resident enterprise for China income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders."

Pursuant to the EIT Law and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in China, or has set up an organization or establishment but the income derived

151

[Table of Contents](#)


has no actual connection with such organization or establishment, it will be subject to a withholding tax on its Chinese-sourced income at a rate of 10%. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, the tax rate in respect to dividends paid by a Chinese enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the Chinese enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements ("SAT Circular 81"), a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced tax rate: (i) it must directly own the required percentage of equity interests and voting rights in the Chinese resident enterprise; and (ii) it must have directly owned such percentage in the Chinese resident enterprise throughout the 12 months prior to receiving the dividends. Additionally, China has started an anti-tax treaty shopping practice since the issuance of Circular 601 in 2009. On February 3, 2018, the State Administration of Taxation released the Announcement on Issues concerning the "Beneficial Owner" in Tax Treaties ("PN9"), which provides guidelines in determining a beneficial owner qualification under dividends, interest and royalty articles of tax treaties. Chinese tax authorities in general often scrutinize fact patterns case by case in determining foreign shareholders' qualifications for a reduced treaty withholding tax rate, especially against foreign companies that are perceived as being conduits or lacking commercial substance. Furthermore, according to the Administrative Measures for Non-Resident Enterprises to Enjoy Treatments under Tax Treaties, which became effective in January 2020, where non-resident enterprises judge by themselves that they meet the conditions for entitlement to reduced tax rate according to tax treaties, they may enjoy such entitlement after reporting required information to competent tax authorities provided that they shall collect and retain relevant documents for future reference and inspections. Accordingly, our ShouTi Hong Kong Ltd. subsidiary Subsidiary may be able to enjoy the 5% tax rate for the dividends it receives from its Chinese incorporated subsidiaries if they satisfy the conditions prescribed under SAT Circular 81, PN9 and other relevant tax rules and regulations and complete the necessary government formalities. However, according to SAT Circular 81, if the relevant tax

152

[Table of Contents](#)

authorities determine our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable tax rate on dividends in the future.

If our Cayman Islands holding company, Structure Therapeutics Inc., is not deemed to be a Chinese resident enterprise, holders of our ordinary shares and ADSs who are not Chinese residents will not be subject to Chinese income tax on dividends distributed by us. With respect to gains

realized from the sale or other disposition of the shares or ADSs, there is a possibility that a Chinese tax authority may impose an income tax under the indirect transfer rules set out under 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"), except that such transaction could fall under the safe harbor thereunder. See Part I, Item 1A. "Risk Factors  Risks Related to Doing Business in China and Our International Operations-We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises."

Material U.S. Federal Income Tax Consequences

The following is a summary of the material U.S. federal income tax consequences to U.S. holders and non-U.S. holders (each, as defined below) of the acquisition, ownership and disposition of our ordinary shares or ADSs. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, and does not address the potential application of the Medicare contribution tax or the alternative minimum tax, the impact of special tax accounting rules under Section 451(b) of the Code, any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), all as in effect as of the date of this Annual Report. These authorities are subject to change and to differing interpretations, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

152

[Table of Contents](#)

This discussion is limited to holders who hold our ordinary shares or ADSs as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;

153

[Table of Contents](#)

- persons who acquire our ordinary shares or ADSs through the exercise of an option or otherwise as compensation;
- persons that own, or have owned, actually or constructively, more than 5% of our ordinary shares or ADSs;

- persons who have elected to mark securities to market;
- U.S. expatriates; and
- persons holding our ordinary shares or ADSs as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR ORDINARY SHARES OR ADSs, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of U.S. Holder and Non-U.S. Holder

A U.S. holder is any U.S. person that is a beneficial owner of our ordinary shares or ADSs. A U.S. person, for U.S. federal income tax purposes, is any of the following:

- an individual citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;

153

[Table of Contents](#)

- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust, or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our ordinary shares or ADSs that is not a "U.S. person" nor a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our ordinary shares or ADSs and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our ordinary shares or ADSs.

Tax Classification of the Company as a U.S. Domestic Corporation

For U.S. federal income tax purposes, a corporation is generally considered to be a tax resident in the jurisdiction of its organization or incorporation. Accordingly, under the generally applicable U.S. federal income tax rules, the Company, which is incorporated under the laws of the Cayman Islands, would be classified as a non-U.S. corporation (and, therefore, not a U.S. tax resident) for U.S. federal income tax purposes. However, Section 7874 of the Code provides an exception to this general rule, under which a non-

154

[Table of Contents](#)

U.S. non-U.S. incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes. These rules are complex and there is limited guidance regarding their application. A number of significant and complicated U.S. federal income tax

consequences may result from such classification, and this summary does not attempt to describe all such U.S. federal income tax consequences. Section 7874 of the Code and the Treasury Regulations promulgated thereunder do not address all the possible tax consequences that arise from the Company being treated as a U.S. domestic corporation for U.S. federal income tax purposes. Accordingly, there may be additional or unforeseen U.S. federal income tax consequences to the Company that are not discussed in this summary.

Under such rules, even though the Company is organized as a Cayman Islands corporation, it will be treated as a U.S. domestic corporation for U.S. federal income tax purposes as a result of the Company's prior acquisition of a United States target corporation and application of the so-called "inversion" rules under Section 7874 of the Code. As such, the Company will be subject to U.S. federal income tax as if it were organized under the laws of the United States or a state thereof, and its dividends will be treated as dividends from a U.S. corporation. In addition, the Company will be required to file a U.S. federal income tax return annually with the IRS. It is anticipated that such U.S. tax treatment will continue indefinitely and that our ordinary shares and ADSs will be treated indefinitely as shares in a U.S. domestic corporation for U.S. federal income tax purposes. The Company's status as a domestic corporation for U.S. federal income tax purposes has implications for all shareholders, although only the application to U.S. Holders is discussed in this summary.

The remaining discussion contained in this section titled "Material U.S. Federal Income Tax Considerations" section assumes that the Company will be treated as a domestic corporation for all U.S. federal income tax purposes.

Tax Considerations for U.S. Holders

Distributions

154

[Table of Contents](#)

It is unlikely that we will pay any dividends on our ordinary shares or ADSs in the foreseeable future. If we make cash or other property distributions on our ordinary shares or ADSs, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our ordinary shares or ADSs, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our ordinary shares and will be treated as described under "-Sale or Redemption" below. Distributions constituting dividend income to U.S. holders that are individuals may qualify for reduced rates applicable to qualified dividend income. Distributions constituting dividend income to U.S. holders that are U.S. corporations may qualify for the dividends received deduction.

Sale or Redemption

A U.S. holder will generally recognize capital gain or loss on a sale, exchange, redemption (other than a redemption that is treated as a distribution) or other disposition of our ordinary shares or ADSs equal to the difference between the amount realized upon the disposition and the U.S. holder's adjusted tax basis in the shares so disposed. Such capital gain or loss will be a long-term capital gain or loss if the U.S. holder's holding period for the shares disposed of exceeds one year at the time of disposition. Long-term capital gains of non-corporate taxpayers are generally taxed at a lower maximum marginal tax rate than the maximum marginal tax rate applicable to ordinary income. The deductibility of net capital losses by individuals and corporations is subject to limitations.

Foreign Currency

The amount of any distribution paid to a U.S. holder in foreign currency, or the amount of proceeds paid in foreign currency on the sale, exchange or other taxable disposition of our ordinary shares or ADSs, generally

155

[Table of Contents](#)

will be equal to the U.S. dollar value of such foreign currency based on the exchange rate applicable on the date of receipt (regardless of whether such foreign currency is converted into U.S. dollars at that time). A U.S. holder will have a basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any U.S. holder who converts or otherwise disposes of the foreign currency after the date of receipt may have a foreign currency exchange gain or loss that would be treated as ordinary income or loss, and generally will be U.S. source income or loss for foreign tax credit purposes. Different rules apply to U.S. holders who use the accrual method of tax accounting. Each U.S. holder should consult its own tax advisors concerning issues related to foreign currency.

Information Reporting and Backup Withholding

Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of ordinary shares or ADSs payable to a U.S. Holder. Certain U.S. holders may be subject to backup withholding with respect to the payment of dividends and certain payments of proceeds on the sale or redemption of ordinary shares or ADSs unless such U.S. holder provides proof of an applicable exemption or a correct taxpayer identification number (usually with an IRS Form W-9), and otherwise comply with applicable requirements of the backup withholding rules.

Backup withholding is not an additional tax. Any amount withheld under the backup withholding rules from a payment to a U.S. holder is allowable as a credit against such U.S. holder's U.S. federal income tax, which may entitle the U.S. holder to a refund, provided that the U.S. holder timely provides the required information to the IRS. Moreover, certain penalties may be imposed by the IRS on a U.S. holder who is required to furnish information but does not do so in the proper manner.

Non-U.S. Holders

Distributions

155

Table of Contents

It is unlikely that we will pay any dividends on our ordinary shares or ADSs in the foreseeable future. If we make cash or other property distributions on our ordinary shares or ADSs, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our ordinary shares, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our ordinary shares and will be treated as described under "Gain On Sale or Redemption" below.

Subject to the discussion below regarding effectively connected income, any dividend income paid to a non-U.S. holder of our ordinary shares or ADSs generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our paying agent a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) including a U.S. taxpayer identification number and certifying such holder's qualification for the reduced rate. This certification must be provided to us or our paying agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our ordinary shares in connection with the conduct of a trade or business in the United States, and dividends paid on our ordinary shares or ADSs are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment in the United

156

[Table of Contents](#)

States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our ordinary shares or ADSs generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding these rules and any applicable income tax treaties that may provide for different rules.

Sale or Redemption

Subject to the discussion below regarding backup withholding and Sections 1471 to 1474 of the Code ("FATCA"), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our ordinary shares or ADSs, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our ordinary shares or ADSs constitute a "United States real property interest" by reason of our status as a United States real property holding corporation, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding

156

[Table of Contents](#)

period for our ordinary shares or ADSs, and our ordinary shares or ADSs, as applicable, are not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Determining whether we are a United States real property holding corporation in the third bullet point above depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and do not anticipate becoming a United States real property holding corporation for U.S. federal income tax purposes but cannot give assurance that we are not or will not become a United States real property holding corporation. Even if we are or were to become a United States real property holding corporation, gain arising from the sale or other taxable disposition by a non-U.S. holder of our ordinary shares or ADSs will not be subject to U.S. federal income tax on transfers of United States real property holding corporation shares if the ordinary shares or ADSs are "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of the

[Table of Contents](#)

ordinary shares or ADSs, as applicable, throughout the shorter of, the five-year period ending on the date of the sale or other taxable disposition or, the Non-U.S. holder's holding period. We do not expect that our ordinary shares will be treated as regularly traded on an established securities market, and there can be no assurance that our ADSs will qualify or continue to qualify as regularly traded on an established securities market. If any gain on a non-U.S. holder's disposition is taxable because we are a United States real property holding corporation and our ordinary shares or ADSs are not treated as regularly traded on an established securities market, the non-U.S. holder will be taxed on such disposition generally in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business (subject to the provisions under an applicable income tax treaty), except that the branch profits tax generally will not apply.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of dividends on our ordinary shares or ADSs paid to such holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our ordinary shares or ADSs provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

[Table of Contents](#)

Withholding on Foreign Entities or Accounts

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes.

FATCA applies to dividends paid on our ordinary shares and ADSs. Proposed regulations issued by the Treasury Department (on which taxpayers are entitled to rely until final regulations are issued) eliminate the federal withholding tax of 30% imposed by FATCA to gross proceeds of a sale or other disposition of our ordinary shares or ADSs. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this FATCA on their investment in our ordinary shares or ADSs.

[Table of Contents](#)
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should carefully read, consider, and evaluate the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included in Part II. Item 8 "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K ("Annual Report"). This discussion and other parts of this Annual Report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, which 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. Please also see the section titled "Cautionary Note Regarding Forward-Looking Statements." Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part I. Item 1A. "Risk Factors."

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 approximately \$166.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. In September 2023, we entered into a share purchase agreement with certain institutional investors (the "Purchase Agreement"), pursuant to which we issued and sold an aggregate of 21,617,295 ordinary shares and 2,401,920 non-voting ordinary shares for net proceeds of approximately \$281.5 million (the "Private Placement").

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 GSB-1290, our oral small molecule product candidate targeting the validated GLP-1R glucagon-like-peptide-1 receptor ("GLP-1R") for the treatment of type 2 diabetes mellitus ("T2DM") and obesity. We completed our Phase 1 single ascending dose ("SAD") study of GSB-1290 in September 2022. GSB-1290 was generally well tolerated and demonstrated dose-dependent 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 of GSB-1290 in January 2023 and completed dosing in otherwise healthy overweight subjects in March 2023. We plan to submit In May 2023, we submitted a protocol amendment to the FDA to transition to a and initiated dosing of the Phase 2a proof-of-concept study in T2DM and obesity. We reported topline data for the 28-day Phase 1b MAD study in September 2023, in which GSB-1290 was generally well-tolerated with no adverse event-related discontinuations and demonstrated an encouraging safety profile and significant weight loss of up to 4.9% placebo-adjusted, supporting once-daily dosing. In December 2023, we reported clinically meaningful topline data from our Phase 2a T2DM cohort, interim results from our Phase 2a obesity cohort and topline data from a Japanese ethno-bridging study of GSB-1290. These data demonstrated that GSB-1290 was generally well-tolerated, with no treatment-related SAEs over 12 weeks, with only one participant discontinuing the study due to adverse events in the T2DM cohort and none in the obesity cohort. GSB-1290 also showed significant reduction in weight in the obesity cohort at 8 weeks, and significant reductions in hemoglobin A1c ("HbA1c") and weight in the T2DM cohort. We expect to report the full 12-week Phase 2a obesity data in the latter half of the second quarter of 2024 with additional 24 participant data. We also fully enrolled a formulation bridging and titration optimization study to evaluate capsule versus tablet PK and explore different titration regimens of GSB-1290. This study is expected to be

completed in the latter half of the second quarter of 2024, in preparation for the global Phase 2b study for obesity which we expect to initiate in the fourth quarter of 2024. A Phase 2 study in T2DM is also planned for the second half of 2023. We expect to report topline data for the Phase 1b study and Phase 2a study with the expected initiation in the second half of 2023. Beyond GSB-1290, we are developing next generation GLP-1R candidates, including dual GLP-1R/GIPR agonists, each designed with customized properties to achieve additional benefit. 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 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.

159

Table of Contents

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



Graphic

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. We have established a manufacturing plan in the U.S. and continue to contract in parallel with additional suppliers in the US and other regions outside of China to diversify the manufacturing of our active pharmaceutical ingredient and drug product. 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 \$51.3 \$89.6 million and \$38.0 \$51.3 million in the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of \$117.0 \$206.6 million. As of December 31, 2022, Historically, we have financed our operations primarily through the private placement of equity securities and have received aggregate gross proceeds of approximately \$198.0 million, and have cash, cash equivalents and short-term investments of \$90.8 million. On February 7, 2023, securities. In February 2023, we completed our initial public offering ("IPO") 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. In

September 2023, we entered into a share purchase agreement with certain institutional investors (the "Purchasers"), pursuant to which we agreed to sell and issue to the Purchasers an aggregate of 21,617,295 ordinary shares and 2,401,920 newly designated non-voting ordinary shares at a purchase price of \$12.49 per share (or the equivalent of \$37.47 per ADS), the closing price of our ADS on the Nasdaq Global Market on September 28, 2023. We completed the Private Placement in October 2023 and received approximately \$281.5 million in net proceeds after deducting placement agent fees and other private placement expenses.

As of December 31, 2023, we have cash, cash equivalents and short-term investments of \$467.3 million. Based on our current business plan, we estimate that our existing cash, cash equivalents and short-term

160

[Table of Contents](#)

investments together with the net proceeds from our IPO, will be sufficient to fund our projected operations through at least 2025, 2026. 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

160

[Table of Contents](#)

and commercialize any approved product candidates. In addition, following the closing of our IPO, 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 Securities Exchange Commission ("SEC") 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 the ongoing COVID-19 pandemic 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 the COVID-19 Pandemic Geopolitical and Other Macroeconomic Factors

In December 2019,

Although we did not see a novel strain significant financial impact to our business operations as a result of coronavirus (including its variants, "COVID-19") 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 year ended December 31, 2023, was reported in China. Since then, COVID-19 has spread globally. The spread of COVID-19 from China there may be potential impacts to other countries has resulted our business in the World Health Organization ("WHO") declaring the outbreak of COVID-19 as a pandemic. Many countries around the world had imposed quarantines future that are highly uncertain and restrictions on travel and mass gatherings difficult to slow the spread of the virus and had closed non-essential businesses. If local jurisdictions continue to put restrictions in place, predict, including our ability to continue raise additional funds, disruptions to operate our business may also be limited. Such events may result in a period of business, supply and research activities' disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

To date, we have 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. However, we cannot, at this time, predict the specific extent, duration or full impact that the COVID 19 pandemic will continue to have on our financial condition and operations, including our ongoing and planned preclinical studies and clinical trials. While the pandemic appears to have waned, there may be significant uncertainty resulting from any changes with regards to COVID-19 infections, along with the impact of other macroeconomic factors such as inflation, supply chain issues, rising interest rates, future bank failures and the impact of the Russian/Ukraine conflict. The impact of related responses and disruptions caused by the COVID-19 pandemic as well as prevailing macroeconomic factors has and may in the future More specifically, the COVID 19 pandemic could disrupt 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, impede impediments to our clinical trial initiation and recruitment, errors or omissions at our clinical sites and the ability of patients to continue in clinical trials, and cause delays in the FDA's review and approval processes, any of our ability to effectively operate across different geographies in which could delay our preclinical studies and clinical trials and increase our development costs.

In addition, the spread of COVID 19, which has caused a broad impact globally, and other macroeconomic factors, may materially affect us economically. While the potential economic impact brought by, and the duration of, any continuing impact of COVID 19 and the impact of macroeconomic factors may be difficult to assess or predict, a widespread pandemic, actual or anticipated changes offices are located, continued increases in interest rates and economic

161

[Table of Contents](#)

inflation, current and future bank failures, and the impact of on the Russian/Ukraine conflict has caused global economy due to the Israel-Hamas war, higher prices of supplies, declines and changes in global confidence availability and could result in significant disruption cost of global financial markets, reducing credit and our ability to access capital, which could in the future negatively affect our liquidity, or make any necessary financing more costly or more dilutive. In addition, a recession or market correction resulting from the spread capital. The ultimate impact of COVID 19 these geopolitical and such macroeconomic factors, could materially affect as well as any lasting effects on the way we conduct our business. Possible effects of COVID-19 business, is highly uncertain and subject to continued change, and we recognize that they may also include absenteeism in our labor workforce and unavailability of products and supplies used in operations. 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 ("Schrö (together with its affiliates, "Schrödinger") to discover and develop novel, orally bioavailable, small molecule inhibitors of LPA1R. lysophosphatidic acid 1 receptor ("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

161

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 December 31, 2022 December 31, 2023, we have paid to Schrödinger an aggregate of \$0.8 million. If Lhotse develops and commercializes a product containing a compound (a "Collaboration Lhotse Collaboration Compound"), that is discovered or developed under the Lhotse-Schrödinger Agreement (a "Collaboration Lhotse 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 Lhotse Collaboration Products that reach such milestones. Lhotse will also be obligated to pay Schrödinger tiered royalties on a Lhotse Collaboration Product-by-Collaboration Product-by-Lhotse Collaboration Product basis equal to low single digit percentages on aggregate worldwide net sales of Lhotse Collaboration Products, subject to specified reductions and offsets. Lhotse's obligation to pay royalties to Schrödinger will expire on a Lhotse Collaboration Product-by-Collaboration Product-by-Lhotse 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 Lhotse Collaboration Compound contained in such Lhotse Collaboration Product in such country, (ii) the expiration of regulatory, pediatric, orphan drug, or data exclusivity with respect to such Lhotse Collaboration Product in such country, and (iii) ten years after the first commercial sale of such Lhotse Collaboration Product in such country (the "Royalty Lhotse 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 December 31, 2023, no milestone or royalty payments have been paid or accrued.

Aconcagua Collaboration Agreement with Schrödinger

In November 2023, Aconcagua Bio, Inc., our wholly-owned subsidiary ("Aconcagua"), entered into a collaboration agreement (the "Aconcagua-Schrödinger Agreement") with Schrödinger to discover and develop novel, small molecule modulators of a specific target. Under the Aconcagua-Schrödinger Agreement, Schrödinger is obligated to provide computational modeling and design support, including by using its technology platform to perform virtual screens, and Aconcagua is obligated to provide day-to-day chemistry and biology support. Pursuant to the Aconcagua-Schrödinger Agreement, a joint steering committee comprised of representatives from both parties oversees the research performed under the agreement. During the term of the Aconcagua-Schrödinger Agreement or if longer, for a specified number of years after the effective date of the Aconcagua-Schrödinger Agreement, Schrödinger is obligated, subject to certain exceptions, to work exclusively with Aconcagua on the design, research, development and commercialization of compounds that inhibit the target. Aconcagua will solely own the research results, work product, inventions and other intellectual property generated under the Aconcagua-Schrödinger Agreement other than improvements to Schrödinger's background intellectual property.

During the term of the Aconcagua-Schrödinger Agreement, Aconcagua is obligated to pay Schrödinger a monthly active program payment in the low six digits, which payment includes fees payable for certain Schrödinger software employed in the Collaboration, and as of December 31, 2023, we have paid to Schrödinger an aggregate of \$0.3 million. If Aconcagua develops and commercializes a product containing a compound ("Aconcagua Collaboration Compound") that is discovered or developed under the Aconcagua-Schrödinger Agreement or a derivative thereof ("Aconcagua Collaboration Product"), Aconcagua is obligated

to pay Schrödinger development, regulatory and commercialization milestone payments of up to an aggregate of \$89.0 million for the first Aconcagua Collaboration Product to achieve a particular milestone event, regardless of the number of Aconcagua Collaboration Products that reach such milestones. Aconcagua will also be obligated to pay Schrödinger tiered royalties in the low single digit range on aggregate worldwide net sales of all Aconcagua Collaboration Products, subject to specified reductions and offsets. Aconcagua's obligation to pay royalties to Schrödinger will expire on a Aconcagua Collaboration Product-by- Aconcagua Collaboration Product and country-by-country basis on the later of (i) the expiration of the last-to-expire Aconcagua owned patent claim covering the composition of matter of the Aconcagua Collaboration Compound contained in such Aconcagua Collaboration Product in such country and (ii) ten years after the first commercial sale of such Aconcagua Collaboration Product in such country ("Aconcagua Royalty Term").

Unless terminated earlier, the Aconcagua-Schrödinger Agreement will continue for three years, subject to extension by mutual written agreement of the parties. Either party may terminate the Aconcagua-Schrödinger Agreement for convenience after a specified period or for the other party's uncured material breach. Aconcagua's obligation to make milestone and royalty payments (subject to the Aconcagua Royalty Term) to Schrödinger continues after the expiration or termination of the Aconcagua-Schrödinger Agreement, unless the Aconcagua-Schrödinger Agreement is terminated under specified circumstances. As of December 31, 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 impact of data collection omissions at any of our clinical sites;
- 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, especially in light of the ongoing COVID-19 pandemic; 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.

163

[Table of Contents](#)

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 amortization of discounts and premiums on short-term investments, foreign currency exchange gains and losses and interest expense for the amortization of debt issuance costs.

164

[Table of Contents](#)

Results of Operations

Comparison of the Years Ended December 31, 2022 December 31, 2023 and 2021 2022

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

	YEAR ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2022	2021	2023	2022
Operating expenses:				
Research and development	\$ 36,193	\$ 29,111	\$ 70,103	\$ 36,193
General and administrative	16,368	8,585	32,672	16,368
Total operating expenses	52,561	37,696	102,775	52,561
Loss from operations	(52,561)	(37,696)	(102,775)	(52,561)
Interest and other income (expense), net	1,257	(122)	13,391	1,257
Loss before provision for income taxes	(51,304)	(37,818)	(89,384)	(51,304)
Provision for income taxes	17	231	236	17
Net loss	\$ (51,321)	\$ (38,049)	\$ (89,620)	\$ (51,321)

Research and Development Expenses

Research and development expenses increased by \$7.1 \$33.9 million, or 24% 94%, to \$36.2 million \$70.1 million during the year ended December 31, 2022 December 31, 2023, compared to \$29.1 \$36.2 million during the year ended December 31, 2021 December 31, 2022. The

164

[Table of Contents](#)

increase in research and development expenses was primarily due to the advancement of our GLP-1R franchise and other research programs, clinical study activities and increases related to employee expenses, primarily due to an increase in employee related expenses, consulting and laboratory expenses, as we increased our staffing and development efforts, personnel.

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

	YEAR ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2022	2021	2023	2022
Product candidate:				
ANPA-0073	\$ 3,383	\$ 7,251	\$ 3,521	\$ 3,383
GSBR-1290	18,791	11,697	44,763	18,791
LTSE-2578	4,936	4,585	4,853	4,936
Other	9,083	5,578	16,966	9,083
Total research and development expenses	\$ 36,193	\$ 29,111	\$ 70,103	\$ 36,193

General and Administrative Expenses

General and administrative expenses increased by \$7.8 million \$16.3 million, or 91% 100%, to \$32.7 million during the year ended December 31, 2023, compared to \$16.4 million during the year ended December 31, 2022, compared to \$8.6 million during the year ended December 31, 2021. 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 to prepare to become as a publicly-traded company.

[Table of Contents](#)

Interest and Other Income (Expense), Net

Interest and other income (expense), net, increased by ~~\$1.4 million~~ ~~\$12.1 million to an income of \$13.4 million during the year ended December 31, 2023, compared~~ to an income of \$1.3 million during the year ended December 31, 2022, ~~compared to an expense of \$0.1 million during the year ended December 31, 2021~~. The increase in interest and other income (expense), net, was primarily due to an increase in interest income from higher interest ~~rates, rates and cash, cash equivalents and short-term investment balances~~.

Liquidity and Capital Resources

~~Since we were reorganized~~ ~~From our reorganization~~ as a Cayman Islands exempted company in February 2019 through ~~December 31, 2022, immediately prior to completion of our IPO, we have~~ funded our operations primarily with an aggregate of \$198.0 million in gross cash proceeds from the sale of redeemable convertible preferred shares. ~~In February 2023, we completed our IPO and received \$166.7 million in net proceeds after deducting underwriting discounts and commissions and estimated offering costs. In October 2023, we completed our Private Placement and received \$281.5 million in net proceeds after deducting placement agent fees and other private placement expenses. As of December 31, 2022~~ ~~December 31, 2023, we had cash, cash equivalents and short-term investments of \$90.8~~ ~~\$467.3 million and an accumulated deficit of \$117.0 million~~ ~~\$206.6 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.

[Table of Contents](#)

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

As of December 31, 2022, 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 as of December 31, 2022, million. Since our inception, we have incurred net operating losses and negative cash flows from operations. We had net losses of \$51.3 \$89.6 million and \$38.0 million \$51.3 million in the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of \$117.0 \$206.6 million. In February 2023, we completed our IPO for net proceeds of \$166.7 million. In October 2023, we completed our Private Placement and received \$281.5 million in net proceeds after deducting placement agent fees and other private placement expenses. 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 December 31, 2022 December 31, 2023, we had cash, cash equivalents and short-term investments of \$90.8 million \$467.3 million. Based on our current business plan, we believe that our existing cash, cash equivalents and short-term investments together with the net proceeds from our IPO, will be sufficient to fund our projected operations for the next 12 months from the date of the issuance of our 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.

[Table of Contents](#)

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, following the closing of our IPO, 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 **it we** may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

166

[Table of Contents](#)

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 **the COVID 19 pandemic**, future bank failures, **increased geopolitical tensions between the U.S. and China**, the Russia/Ukraine conflict, **the Israel-Hamas war and global pandemics** on U.S. and global economic conditions that may impact our ability to access capital on **acceptable** terms, **acceptable, or 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

167

[Table of Contents](#)

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 the ongoing COVID-19 pandemic or other geopolitical and macroeconomic events such as actual or anticipated changes in interest rates and economic inflation, future bank failures, global pandemics, geopolitical tensions between the U.S. and China and the impact of the Russian/Russia/Ukraine conflict, conflict and the Israel-Hamas war. If we are unable

167

[Table of Contents](#)

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):

	YEAR ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2022	2021	2023	2022
Net cash (used in) provided by:				
Operating activities	\$ (46,120)	\$ (32,160)	\$ (79,488)	\$(46,120)
Investing activities	(62,108)	17,859	(268,342)	(62,108)
Financing activities	29,014	103,254	451,531	29,014
Net (decrease) increase in cash and cash equivalents	\$ (79,214)	\$ 88,953		
Net increase (decrease) in cash and cash equivalents			\$ 103,701	\$(79,214)

Cash Flows Used in Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was \$79.5 million, consisting primarily of a net loss of \$89.6 million, partially offset by non-cash charges of \$3.2 million and a decrease in net operating assets of \$7.0 million. The increase in net loss was primarily due to 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, partially offset by net gain from accretion of net investment discounts. 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 year ended December 31, 2022, net cash used in operating activities was \$46.1 million, consisting primarily of a net loss of \$51.3 million, partially offset by non-cash charges of \$2.2 million and a decrease in net operating assets of \$3.0 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 prepared to become a publicly-traded company. Non-cash charges consisted primarily of share-based compensation. The decrease in net operating assets was primarily due to increases in accounts payable and accrued expenses and other current liabilities.

Cash Flows Used in Investing Activities

During the year ended December 31, 2021, net cash used in operating investing activities was \$32.2 million \$268.3 million, consisting primarily of a net loss purchases of \$38.0 million, partially offset by non-cash charges short-term investments of \$1.8 million \$266.2 million and a decrease in net operating assets purchases of \$4.0 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 property and development efforts. Non-cash charges consisted

primarily equipment of share-based compensation. The decrease in net operating assets is primarily due to increases in accrued expenses and other current liabilities and accounts payable, partially offset by an increase in prepaid expenses and other current assets.

168

[Table of Contents](#)

Cash Flows (Used in) Provided by Investing Activities \$2.1 million.

During the year ended December 31, 2022, net cash used in investing activities was \$62.1 million, consisting primarily of net purchases of short-term investments.

During the year ended December 31, 2021, net cash provided by investing activities was \$17.9 million, consisting primarily of net maturities of short-term investments of \$19.1 million, partially offset by purchases of property and equipment of \$1.2 million.

Cash Flows Provided by Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities was \$451.5 million, consisting primarily of proceeds from our IPO of \$172.3 million, net of underwriting discounts and

168

[Table of Contents](#)

commissions, gross proceeds from our Private Placement of \$300.0 million, partially offset by payments of offering costs of \$21.6 million.

During the year ended December 31, 2022, net cash provided by financing activities was \$29.0 million, consisting primarily of net proceeds from the issuance of our Series B redeemable convertible preferred shares, partially offset by payments of deferred offering costs.

During the year ended December 31, 2021, net cash provided by financing activities was \$103.3 million, consisting primarily of net proceeds from the issuance of our Series B redeemable convertible preferred shares and Series Seed redeemable convertible preferred shares of Basecamp Bio.

Contractual Obligations

As of December 31, 2022 December 31, 2023, our contractual obligations consist of facilities lease payments totaling \$0.3 million through October 31, 2023. \$6.1 million, with \$1.8 million expected to be paid within the next 12 months.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The preparation of our 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 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates, performance. For more detail on our significant accounting policies, refer to Note 2 to our consolidated financial statements included in Part II. Item 8 "Financial Statements and Supplementary Data" of this Annual Report.

Share-Based Compensation

We use a fair value-based method to account for all share-based compensation arrangements with employees and non-employees, including share options and share awards. Our determination of the fair value of share options on the date of grant utilizes the Black-Scholes option pricing model.

We recognize the fair value of the options granted on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. We account for forfeitures as they occur.

Estimates of the fair value of equity awards as of the grant date using valuation models such as the Black-Scholes option pricing model are affected by assumptions with a number of complex variables. Changes in certain assumptions can materially affect the fair value and ultimately the amount of share-based

169

[Table of Contents](#)

compensation expense recognized. These inputs are subjective and generally require significant analysis and judgment to develop. The assumptions are as follows:

- **Fair Value of Ordinary Shares**—see the subsection titled “—Ordinary Shares Valuation” below.
- **Expected Term**—The expected term represents the period that the share-based awards are expected to be outstanding. The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.
- **Expected Volatility**—For all share options granted to date, we estimated the volatility data based on a study of publicly traded industry peer companies as we did not have any trading history for our ordinary shares. For purposes of identifying these peer companies, we considered the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, we measured historical volatility over a period equivalent to the expected term. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.
- **Risk-Free Interest Rate**—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.
- **Expected Dividend Yield**—We assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.

See Note 11 to our audited consolidated financial statements included in Part II, Item 8 “Financial Statements and Supplementary Data” of this Annual Report for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2022 and 2021.

Ordinary Shares Valuation

Prior to the completion of our IPO, the estimated fair value of the ordinary shares underlying our share options and share awards was determined at each grant date by our board of directors, with input from management and an independent third-party valuation firm. All options to purchase shares of our ordinary shares are intended to be exercisable at a price per share not less than the per-share fair value of our ordinary shares underlying those options on the date of grant.

In the absence of a public trading market for our ordinary shares, on each grant date, we develop an estimate of the fair value of our ordinary shares based on the information known to us on the date of grant, upon a review of any recent events and their potential impact on the estimated fair value per share of the ordinary shares, and in part on contemporaneous input from an independent third-party valuation firm. Our estimate of fair value is reviewed and approved by our board of directors.

We determined our valuations of our ordinary shares in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the “Practice Aid”). We based the

assumptions used to determine the estimated fair value of our ordinary shares on numerous objective and subjective factors, combined with management judgment, including:

- our most recently available valuations of our ordinary shares performed by an independent third-party valuation firm;

170

[Table of Contents](#)

- the prices at which we sold shares of our redeemable convertible preferred shares;
- the rights, preferences and privileges of our redeemable convertible preferred shares relative to those of our ordinary shares;
- lack of marketability of our common shares as a private company;
- our stage of development and business strategy, and material risks related to our business;
- our financial condition and operating results, including our levels of available capital resources;
- the progress of our research and development efforts;
- the hiring of key personnel and the experience of management;
- the likelihood of achieving a liquidity event given prevailing market conditions;
- external market conditions affecting the pharmaceutical and biotechnology industry and trends within the industry; and
- the valuation of comparable public companies.

For all options granted through December 31, 2022, our board determined the enterprise value based on the Market Approach, Option Pricing Method ("OPM") and Probability Weighted Expected Return Method ("PWERM") or a weighted combination of the OPM and PWERM methods. Under the Market Approach, we estimate the value based upon our prior sales of preferred stock to unrelated third parties. We then apply these derived multiples or values to our financial metrics to estimate our market value. The allocation of these enterprise values to each part of our capital structure, including our ordinary shares, was done based on the OPM. The OPM treats the rights of the holders of preferred and ordinary shares as equivalent to call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred shares, as well as their rights to participation and conversion. Thus, the estimated value of the ordinary share can be determined by estimating the value of its portion of each of these call option rights. The OPM derives the implied equity value of a company from a recent transaction involving our own securities issued on an arms-length basis. Under the PWERM, the value is estimated based upon analysis of future values for the enterprise under varying scenarios, and probabilities are ascribed to these scenarios based on expected future outcomes.

Subsequent to our IPO, the fair value of our ordinary shares is determined based on our closing market price of the Company's ADS, which each represents three ordinary shares.

Accrued Research and Development Expenses

We have entered into various agreements with contract manufacturing organizations ("CMOs") and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in other current liabilities on the balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets on the balance sheets until the services are rendered. To date, our estimated accruals have not differed materially from the actual costs.

Redeemable Convertible Preferred Shares

We record all shares of our redeemable convertible preferred shares at their respective fair values on the dates of issuance, net of issuance costs. The fair value of Series B-1 redeemable convertible preferred shares issued in the Basecamp Bio share exchange agreement was estimated using various fair value measures of classes of preferred stock calculated as part of the valuation of our ordinary shares. In the event of the voluntary or involuntary liquidation, dissolution or winding up of our company, or a liquidation event

171

[Table of Contents](#)

such as a merger, acquisition and sale of all or substantially all of our assets, each of which we refer to as a deemed liquidation event, proceeds will be distributed in accordance with the liquidation preferences set forth in our amended and restated memorandum and articles of association unless the holders of redeemable convertible preferred shares have converted their redeemable convertible preferred shares into ordinary shares. Therefore, the redeemable convertible preferred shares are recorded in mezzanine equity on our balance sheets as events triggering the liquidation preferences are not solely within our control. We made an accounting policy election to recognize changes in the redemption value of redeemable convertible preferred shares immediately as they occur and adjust the carrying value of redeemable convertible preferred shares to equal its redemption value at the end of each reporting period.

JOBES 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

169

[Table of Contents](#)

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 consolidated financial statements included in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report for additional information.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of **December 31, 2022** **December 31, 2023**, we had cash, cash equivalents and short-term investments of **\$90.8** **\$467.3** million, consisting of interest-bearing money market funds, U.S. government bonds, U.S. government agency bonds and corporate debt securities, for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents, we do not believe that a hypothetical 10% increase or decrease in the relative value of interest rates would have a material effect on our consolidated financial statements included in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Transactions conducted in foreign currencies have not had, and are not expected to have, a material effect on our results of operations, financial position or cash flows. Our operating expenses in countries outside the United States, are payable in foreign currencies and

172

Table of Contents

therefore expose us to currency risk. We do not believe that a hypothetical 10% increase or decrease in the relative value of the U.S. dollar to other currencies would have had a material effect on our consolidated financial statements included in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report. We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies.

Credit Risk

We maintain our cash, cash equivalents and short-term investments with several financial institutions, primarily in the United States, and our current deposits are in excess of insured limits. We believe these institutions have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us. We have not experienced any losses on our deposits of cash, cash equivalents and short-term investments to date.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and in the future our clinical trial costs. We do not believe that inflation has had a material effect on our consolidated financial statements included elsewhere in this Annual Report.

173 170

Table of Contents

Item 8. Financial Statements and Supplementary Data

STRUCTURE THERAPEUTICS INC.
INDEX TO FINANCIAL STATEMENTS
Years Ended December 31, 2022 December 31, 2023 and 2021 2022

	Page
Report of Ernst & Young LLP, Independent Registered Public Accounting Firm (PCAOB ID 42)	172
Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm (PCAOB ID 238)	175 173
Consolidated Financial Statements	

Consolidated Balance Sheets	176 174
Consolidated Statements of Operations and Comprehensive Loss	177 175
Consolidated Statements of Redeemable Convertible Preferred Shares Redeemable Noncontrolling Interest and Shareholders' DeficitEquity (Deficit)	176
Consolidated Statements of Cash Flows	177
Notes to Consolidated Financial Statements	178
Consolidated Statements of Cash Flows	179
Notes to Consolidated Financial Statements	180

174 171

[Table of Contents](#)

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors and Shareholders of Structure Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets sheet of Structure Therapeutics Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and December 31, 2023, the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred shares redeemable noncontrolling interest and shareholders' deficit equity (deficit), and of cash flows for the years then year ended including December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, at December 31, 2023, and the results of its operations and its cash flows for the years year then ended, in conformity with accounting principles U.S. generally accepted in the United States of America. accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits, audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant

estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2023.

San Mateo, California

March 8, 2024

172

[Table of Contents](#)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Structure Therapeutics Inc.

Opinion on the Financial Statements

We have audited the consolidated balance sheet of Structure Therapeutics Inc. and its subsidiaries (the "Company") as of December 31, 2022, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred shares and shareholders' deficit and of cash flows for the year ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, financial position of the Company as of December 31, 2022 and the results of its operations and its cash flows for the year ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 30, 2023

We have served as the Company's auditor since 2020. from 2020 to 2023.

175 173

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	DECEMBER 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,091	\$ 105,305
Short-term investments	64,750	2,002
Prepaid expenses and other current assets	2,248	1,943
Total current assets	93,089	109,250
Property and equipment, net	1,031	1,185
Operating right-of-use assets	262	609
Other non-current assets	3,463	111
Total assets	<u>\$ 97,845</u>	<u>\$ 111,155</u>
Liabilities, redeemable convertible preferred shares and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 6,009	\$ 3,484
Accrued expenses and other current liabilities	6,741	4,825
Operating lease liabilities, current portion	260	349
Total current liabilities	13,010	8,658
Operating lease liabilities, net of current portion	—	272
Total liabilities	13,010	8,930
Commitments and contingencies (Note 6)		
Series A redeemable convertible preferred shares—\$0.0001 par value, 19,200 shares authorized, issued and outstanding as of December 31, 2022 and 2021 (liquidation preference of \$32,001 as of December 31, 2022 and 2021)	32,001	32,001
Series A+ redeemable convertible preferred shares—\$0.0001 par value, 12,800 shares authorized, issued and outstanding as of December 31, 2022 and 2021 (liquidation preference of \$26,000 as of December 31, 2022 and 2021)	26,000	26,000
Series B redeemable convertible preferred stock—\$0.0001 par value, 32,857 and 24,702 shares authorized, issued and outstanding as of December 31, 2022 and 2021, respectively (liquidation preference of \$133,015 and \$100,000 as of December 31, 2022 and 2021, respectively)	133,015	100,000
Series B-1 redeemable convertible preferred stock—\$0.0001 par value, 2,161 shares authorized, issued and outstanding as of December 31, 2022 and 2021 (liquidation preference of \$7,000 as of December 31, 2022 and 2021)	8,959	8,959
Shareholders' deficit:		
Ordinary shares—\$0.0001 par value; 432,982 and 441,137 shares authorized as of December 31, 2022 and 2021, respectively; 10,527 and 10,894 shares issued and outstanding as of December 31, 2022 and 2021, respectively	1	1
Additional paid-in capital	1,921	—
Accumulated other comprehensive loss	(110)	—
Accumulated deficit	(116,952)	(64,736)
Total shareholders' deficit	(115,140)	(64,735)
Total liabilities, redeemable convertible preferred shares and shareholders' deficit	<u>\$ 97,845</u>	<u>\$ 111,155</u>

			DECEMBER 31,	
			2023	2022
Assets				
Current assets:				
Cash and cash equivalents	\$	129,792	\$	26,091
Short-term investments		337,531		64,750
Prepaid expenses and other current assets		6,285		2,248
Total current assets		473,608		93,089
Property and equipment, net		3,228		1,031
Operating right-of-use assets		5,136		262
Other non-current assets		45		3,463
Total assets	\$	482,017	\$	97,845
Liabilities, redeemable convertible preferred shares and shareholders' equity (deficit)				
Current liabilities:				
Accounts payable	\$	4,742	\$	6,009
Accrued expenses and other current liabilities		18,558		6,741
Operating lease liabilities, current portion		1,440		260
Total current liabilities		24,740		13,010
Operating lease liabilities, net of current portion		4,013		—
Other non-current liabilities		298		—
Total liabilities		29,051		13,010
Commitments and contingencies (Note 6)				
Series A redeemable convertible preferred shares – \$0.0001 par value, 0 and 19,200 shares authorized, issued and outstanding as of December 31, 2023 and December 31, 2022, respectively (liquidation preference of \$0 and \$32,001 as of December 31, 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 December 31, 2023 and December 31, 2022, respectively (liquidation preference of \$0 and \$26,000 as of December 31, 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 December 31, 2023 and December 31, 2022, respectively (liquidation preference of \$0 and \$133,015 as of December 31, 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 December 31, 2023 and December 31, 2022, respectively (liquidation preference of \$0 and \$7,000 as of December 31, 2023 and December 31, 2022, respectively)		—		8,959
Shareholders' equity (deficit):				
Undesignated shares – \$0.0001 par value; 90,188 and 0 shares authorized as of December 31, 2023 and December 31, 2022, respectively		—		—
Ordinary shares – \$0.0001 par value; 500,000 and 432,982 shares authorized as of December 31, 2023 and December 31, 2022, respectively; 139,220 and 10,527 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively		14		1
Additional paid-in capital		659,003		1,921
Accumulated other comprehensive income (loss)		521		(110)
Accumulated deficit		(206,572)		(116,952)
Total shareholders' equity (deficit)		452,966		(115,140)
Total liabilities, redeemable convertible preferred shares and shareholders' equity (deficit)	\$	482,017	\$	97,845

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

176 174

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

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

	YEAR ENDED DECEMBER 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 36,193	\$ 29,111
General and administrative	16,368	8,585
Total operating expenses	52,561	37,696
Loss from operations	(52,561)	(37,696)
Interest and other income (expense), net	1,257	(122)
Loss before provision for income taxes	(51,304)	(37,818)
Provision for income taxes	17	231
Net loss	(51,321)	(38,049)
Less: Accretion of redeemable convertible preferred shares to their redemption value	(1,515)	(3,757)
Less: Excess of the fair value of the consideration paid over the carrying value of redeemable noncontrolling interest	—	(1,959)
Net loss attributable to ordinary shareholders	\$ (52,836)	\$ (43,765)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (5.51)	\$ (5.38)
Weighted-average ordinary shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	9,584	8,141
Other comprehensive loss:		
Unrealized (loss) gain on investments, net	(110)	1
Total other comprehensive (loss) gain	(110)	1
Comprehensive loss	\$ (51,431)	\$ (38,048)

	YEAR ENDED DECEMBER 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 70,103	\$ 36,193
General and administrative	32,672	16,368
Total operating expenses	102,775	52,561
Loss from operations	(102,775)	(52,561)
Interest and other income (expense), net	13,391	1,257
Loss before provision for income taxes	(89,384)	(51,304)
Provision for income taxes	236	17
Net loss	(89,620)	(51,321)
Less: Accretion of redeemable convertible preferred shares to their redemption value	—	(1,515)
Net loss attributable to ordinary shareholders	\$ (89,620)	\$ (52,836)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (0.81)	\$ (5.51)
Weighted-average ordinary shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	110,198	9,584

Other comprehensive loss:		
Unrealized gain (loss) on investments, net	631	(110)
Total other comprehensive income (loss)	631	(110)
Comprehensive loss	\$ (88,989)	\$ (51,431)

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

177 175

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

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

	REDEEMABLE CONVERTIBLE PREFERRED SHARES								REDEEMABLE		ORDINARY		ADDITIONAL		OTHER		ACCUMULATED		TOTAL	
	SERIES A		SERIES A+		SERIES B		SERIES B-1		NONCONTROLLING	INTEREST	SHARES	SHARES	AMOUNT	CAPITAL	LOSS	DEFICIT	DEFICIT	SHAREHOLDERS'	DEFICIT	
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT												
		SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT											
Balance at December 31, 2020	19,200	\$ 32,001	12,800	\$ 26,000	—	\$ —	—	\$ —	\$ —	—	10,865	\$ 1	\$ —	477	\$ —	(1)	\$ (22,946)	\$ —	(22,469)	
Issuance of Series B redeemable convertible preferred shares, net of issuance costs of \$3,551	—	—	—	—	24,702	96,449	—	—	—	—	—	—	—	—	—	—	—	—	—	
Accretion of Series B redeemable convertible preferred shares to their redemption value	—	—	—	—	—	3,551	—	—	—	—	—	—	(1,038)	—	—	(2,513)	—	—	(3,551)	
Issuance of Series Seed redeemable convertible preferred shares of Basecamp to noncontrolling interest holders, net of issuance costs of \$91	—	—	—	—	—	—	—	—	6,909	—	—	—	—	—	—	—	—	—	—	
Accretion of Series Seed redeemable convertible preferred shares to their redemption value	—	—	—	—	—	—	—	—	91	—	—	—	—	—	—	(91)	—	—	(91)	

Issuance of Series B-1 redeemable convertible preferred shares in exchange of redeemable noncontrolling interest, net of issuance costs of \$115 (including \$1,959 representing the excess of the fair value of Series B-1 redeemable convertible preferred shares over the carrying amount of redeemable noncontrolling interest)	—	—	—	—	—	—	2,161	8,844	(7,000)	—	—	(937)	—	(1,022)	(1,959)
Accretion of Series B-1 redeemable convertible preferred shares to their redemption value	—	—	—	—	—	—	—	115	—	—	—	—	—	(115)	(115)
Issuance of ordinary share upon exercise of vested share options	—	—	—	—	—	—	—	—	—	29	—	11	—	—	11
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	1,487	—	—	1,487
Unrealized gain on investments, net	—	—	—	—	—	—	—	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(38,049)	(38,049)
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)
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 unvested restricted share awards	—	—	—	—	—	—	—	—	—	(450)	—	(6)	—	—	(6)
Issuance of ordinary share upon exercise of vested share options	—	—	—	—	—	—	—	—	—	83	—	33	—	—	33
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	2,514	—	—	2,514
Unrealized loss on investments, net	—	—	—	—	—	—	—	—	—	—	—	—	(110)	—	(110)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(51,321)	(51,321)
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)

	ACCUMULATED															
	REDEEMABLE CONVERTIBLE PREFERRED SHARES								ORDINARY		NON-VOTING		ADDITIONAL	OTHER	TOTAL	
	SERIES A		SERIES A+		SERIES B		SERIES B-1		SHARES		ORDINARY SHARES		PAID-IN	COMPREHENSIVE	ACCUMULATED	SHAREHOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	LOSS	DEFICIT	EQUITY (DEFICIT)
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)
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 unvested restricted share awards	—	—	—	—	—	—	—	—	(450)	—	—	—	(6)	—	—	(6)
Issuance of ordinary share upon exercise of vested share options	—	—	—	—	—	—	—	—	83	—	—	—	33	—	—	33

Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	2,514	—	—	2,514
Unrealized loss on investments, net	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(110)	—	(110)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(51,321)	(51,321)
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	—	—	—	—	—	—	—	—
Exchange of ordinary shares to non-voting ordinary shares	—	—	—	—	—	—	—	—	(7,411)	(1)	7,411	1	—	—	—	—	—
Issuance of ordinary shares and non-voting ordinary shares in private placement financing, net of issuance costs and underwriting discount of \$18,538	—	—	—	—	—	—	—	—	21,617	2	2,401	—	281,457	—	—	—	281,459
Issuance of ordinary shares upon exercise of vested share options	—	—	—	—	—	—	—	—	498	1	—	—	799	—	—	—	800
Conversion of non-voting ordinary shares into ordinary shares	—	—	—	—	—	—	—	—	9,812	1	(9,812)	(1)	—	—	—	—	—
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	8,191	—	—	—	8,191
Unrealized gain on investments, net	—	—	—	—	—	—	—	—	—	—	—	—	—	631	—	—	631
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(89,620)	(89,620)
Balance at December 31, 2023	—	\$ —	—	\$ —	—	\$ —	—	\$ —	139,220	\$ 14	—	\$ —	\$ 659,003	\$	521	\$ (206,572)	\$ 452,966

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

CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

REFINITIV 

Net loss	\$ (89,620)	\$ (51,321)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	8,191	2,514
Depreciation expense	295	277
Accretion of asset retirement obligation	21	—
Non-cash lease expense	634	347
Accretion of net investment discounts	(5,975)	(905)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,037)	(305)
Other non-current assets	15	(60)
Accounts payable	(860)	2,153
Accrued expenses and other current liabilities	12,163	1,541
Operating lease liabilities	(315)	(361)
Net cash used in operating activities	(79,488)	(46,120)
Cash flows from investing activities		
Purchases of short-term investments	(417,356)	(123,453)
Maturities of short-term investments	151,181	61,500
Purchases of property and equipment	(2,167)	(155)
Net cash used in investing activities	(268,342)	(62,108)
Cash flows from financing activities		
Proceeds from issuance of common stock in initial public offering, net of underwriting discount and commissions	172,296	—
Proceeds from issuance of Series B redeemable convertible preferred shares, net of issuance costs	—	31,500
Proceeds from private placement financing, gross	300,000	—
Payments of offering costs	(21,565)	(2,513)
Repurchases of restricted shares	—	(6)
Proceeds from exercise of share options	800	33
Net cash provided by financing activities	451,531	29,014
Net change in cash and cash equivalents	103,701	(79,214)
Cash and cash equivalents		
Beginning of the period	26,091	105,305
End of the period	\$ 129,792	\$ 26,091
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	\$ —
Conversion of non-voting ordinary shares into ordinary shares	\$ 1	\$ —
Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities	\$ 48	\$ —
Operating lease right-of-use assets obtained in exchange for new lease liabilities	\$ 5,508	\$ —
Recognition of asset retirement obligation	\$ 277	\$ —
Deferred offering costs included in accounts payable and accrued expenses and other current liabilities	\$ 53	\$ 854
Accretion of redeemable convertible preferred shares to their redemption value	\$ —	\$ 1,515

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

179177

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of the Business

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, need**. 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.

Prior to the formation of the Company, the operating activities were carried out by the subsidiaries of the Company. Structure Therapeutics USA Inc., a Delaware corporation ("StructureTx US"), was incorporated on June 6, 2016 **(previously known as ShouTi Inc.)**. On January 20, 2017, StructureTx US was reorganized as a limited liability company. Annapurna Bio, Inc. ("Annapurna"), a Delaware corporation, was incorporated on January 26, 2017, and Gasherbrum Bio, Inc. ("Gasherbrum"), a Delaware corporation, was incorporated on April 19, 2017.

On April 18, 2019, Annapurna, Gasherbrum, StructureTx US and the Company entered into a share exchange agreement (the "Share Exchange Agreement"). As a result of the Share Exchange Agreement, StructureTx US, Annapurna and Gasherbrum became wholly-owned subsidiaries of the Company. At the closing of the Share Exchange Agreement on April 18, 2019, the Company issued to the shareholders of Annapurna, Gasherbrum, and StructureTx US an aggregate of 10,766,250 ordinary shares (the "Share Exchange"). On April 19, 2019, ShouTi LLC was converted into ShouTi Inc., a Delaware corporation, which subsequently changed its name to Structure Therapeutics USA Inc. The Share Exchange was accounted for as a capital transaction.

On June 28, 2019, ShouTi Hong Kong Ltd ("ShouTi Hong Kong") was incorporated as a wholly-owned subsidiary of the Company. On July 26, 2019, Shanghai ShouTi Biotechnology Co., Ltd ("ShouTi Shanghai" **Shanghai ShouTi**) was incorporated as a wholly-owned subsidiary of ShouTi Hong Kong. On April 1, 2020, Lhotse Bio, Inc. ("Lhotse") was incorporated as a wholly-owned subsidiary of the Company.

On February 10, 2021, the Company incorporated Basecamp Bio Inc. ("**Basecamp**" **Basecamp Bio**) in the Cayman Islands with a wholly owned subsidiary, Basecamp Bio Hong Kong Limited ("Basecamp HK") in Hong Kong. Shanghai Basecamp Biotechnology Co., Ltd., a wholly owned subsidiary of Basecamp HK, was established on March 26, 2021 in Shanghai, China. The purpose of Basecamp **Bio** is to develop certain of the Company's technologies in Mainland China. **In March 2021, Basecamp issued 7,000,000 Series Seed shares to other investors that are also investors**

On July 11, 2023, Aconcagua Bio, Inc. ("Aconcagua") and Gimigela Bio, Inc. ("Gimigela") were incorporated in the United States as wholly-owned subsidiaries of the Company, which was accounted for as redeemable noncontrolling interest in the consolidated financial statements (see Note 8). In December 2021, the Company acquired the 7,000,000 Series Seed redeemable convertible preferred shares of Basecamp held by the other investors in exchange for 2,161,402 shares of its Series B-1 redeemable convertible preferred shares with Basecamp becoming a wholly owned subsidiary (see Note 8). The Company has consolidated Basecamp since its incorporation. Company.

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries.

Initial Public Offering

On February 7, 2023, In February 2023, the Company closed its initial public offering ("IPO") of American Depositary Shares ("**ADS**" **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

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

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

178

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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. **The consolidated financial statements as of December 31, 2022**

Private Placement

On September 29, 2023, **including** the Company entered into a share purchase agreement with certain institutional investors (the "Purchasers"), pursuant to which the Company agreed to sell and per share amounts, do not give effect issue to the IPO, as it Purchasers an aggregate of 21,617,295 ordinary shares and 2,401,920 newly designated non-voting ordinary shares at a purchase price of \$12.49 per Share (or the equivalent of \$37.47 per ADS), the closing price of its ADS on the Nasdaq Global Market on September 28, 2023 (the "Private Placement"). Each holder of non-voting ordinary shares had the right to convert each non-voting ordinary share held by such holder into one ordinary share, subject to certain beneficial ownership limitations. The Private Placement closed **subsequent to December 31, 2022**, on October 3, 2023, and the Company received \$281.5 million in net proceeds after deducting placement agent fees and other private placement expenses. As of December 31, 2023, all outstanding non-voting ordinary shares had been converted into ordinary shares.

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 **\$117.0** **\$206.6** million as of **December 31, 2022** **December 31, 2023**. **Through December 31, 2022**, **Prior to completion of its IPO**, the Company has financed its operations primarily through the private placement of equity securities. **On February 7, 2023**, **In February 2023**, the Company completed its IPO for net proceeds of approximately \$166.7 million, after deducting underwriting discounts and estimated offering costs.

To date, **In October 2023**, the Company **has no product candidates approved** closed its Private Placement for **sale** net proceeds of approximately \$281.5 million after deducting placement agent fees and therefore the Company has not generated any revenue from its products. The Company has not generated any revenue from collaboration or other agreements. Management expects operating losses and negative cash flows to continue for the foreseeable future, until such time, if ever, that it can generate significant sales from its product candidates currently in development or through collaboration or other agreements. The Company's prospects are subject to risks and uncertainties frequently encountered by companies in the biotechnology industry as discussed in **Note 2**, private placement expenses.

As of **December 31, 2022** **December 31, 2023**, the Company had cash, cash equivalents and short-term investments of **\$90.8** **\$467.3** million. Based on its current business plan, the Company believes that its current cash, cash equivalents and short-term investments **together with the net proceeds from its IPO**, will be sufficient to fund its projected operations for at least 12 months from the date of the issuance of these consolidated financial statements.

Impact of the COVID-19 Pandemic Geopolitical and Other Macroeconomic Factors

The COVID-19 (coronavirus) pandemic, which has impacted worldwide economic activity, poses risks that the Company or its employees, contractors, suppliers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. Although the impact of COVID-19 has not been material to the Company and its operations, the extent to which the COVID-19 pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time. While the pandemic appears to have waned, there **There** may be significant uncertainty resulting from **any changes with regards to COVID-19 infections**, along with the impact of other **geopolitical and**

macroeconomic factors, such as 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 Russian/Russia/Ukraine conflict, conflict and the Israel-Hamas war. No adjustments have been made to these financial statements as a result of these uncertainties.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements and related disclosures have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The 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.

181179

[Table of Contents](#)

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

Use of Estimates

The preparation of 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, Series B-1 redeemable convertible preferred shares valuation, ordinary share valuation prior to the IPO, and related share-based compensation and certain other accrued liabilities. Actual results could differ from those estimates.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of research and development of medicines that target chronic diseases with unmet medical needs. need. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Company's long-lived assets are primarily in China.

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 placing them with investing in investment-grade securities and using banks and institutions it believes are highly creditworthy and in highly rated investments. 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

182

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies.

180

[Table of Contents](#)

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

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 its clinical trial programs. These programs could be adversely affected by a significant interruption in these manufacturing services.

Cash and Cash Equivalents

The Company considers all highly liquid highly-liquid investments purchased with maturities of 90 days or less from the original date of purchase to be cash equivalents. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company's cash and cash equivalents consist of cash deposited with banks and investments in money market funds.

Short-Term Investments

The Company classifies its investments as available-for-sale and records them at fair value based upon market prices at period end. Unrealized gains and losses that are deemed temporary in nature are recorded in accumulated other comprehensive income as a separate component of shareholders' deficit. equity (deficit). Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold. The Company may sell these securities at any time for use in current operations.

Other-Than-Temporary Impairment 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 is 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 evaluates its investments with unrealized losses for other-than-temporary impairment. When assessing investments for other-than-temporary declines in value, has elected to exclude accrued interest from both the Company considers factors such as, among other things, the extent and length of time the investment's fair value has been lower than its cost basis, the financial condition and near-term prospects of the investment, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and the expected cash flows from the security. If any adjustments to fair value reflects a decline in the value amortized cost basis of the investment 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 the Company considers to be "other than temporary," the Company reduces the investment to fair value has not been recorded through a charge to the consolidated statements of operations and an allowance for credit losses is recognized in other comprehensive loss. No such adjustments At December 31, 2023 and 2022, gross unrealized losses on the Company's available-for-sale securities were necessary during the periods presented, not material and, accordingly, no credit loss reserves were recognized.

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 non-

181

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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).

Property and Equipment, Net

Property and equipment, net is stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally two to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. When assets are retired or otherwise disposed of, the cost and

183

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

accumulated depreciation are removed from the balance sheet, and any resulting gain or loss is reflected in operating expenses in the period realized. Maintenance and repairs are charged to operating expenses as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment, net, and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require that a long-lived asset be tested for possible impairment, the Company compares the undiscounted cash flows expected to be generated by the asset group to the carrying amount of the asset group. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. During the years ended **December 31, 2022** **December 31, 2023** and **2021, 2022**, the Company **has did not recorded recognize any such** impairment **charges on its long-lived assets** **charges**.

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 and Private Placements**, 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. **As of December 31, 2022** **Upon closing the IPO and 2021, Private Placement**, all deferred offering costs were **\$3.4 million** charged against the proceeds from the IPO and **\$0.1 million** Private Placement and recorded in shareholders equity (deficit) as a reduction of additional paid-in capital. **As of December 31, 2023 and 2022**, deferred offering costs were \$0 and \$3.4 million, respectively.

Accrued Research and Development Expenses

The Company has entered into various agreements with contract manufacturing organizations ("CMOs") and contract research organizations ("CROs"). The Company's research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in other current liabilities on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets on the consolidated balance sheets until the services are rendered.

182

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Leases

The Company determines if an arrangement is, or contains, a lease at inception and then classifies the lease as operating or financing based on the underlying terms and conditions of the contract. Leases with terms greater than one year are initially recognized on the consolidated balance sheets as right-of-use assets and lease liabilities based on the present value of lease payments over the expected lease term. The Company has also elected to not apply the recognition requirement to any leases within its existing classes of assets with a term of 12 months or less and does not include any options to purchase the underlying asset that the Company is reasonably certain to exercise. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Variable lease payments are excluded from the right-of-use assets and operating lease liabilities and are recognized in the period in which the obligation for those payments is incurred. The Company elected the practical expedient not to separate non-lease components from lease

184

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

components for the Company's facility leases and to account for the lease and non-lease components as a single lease component.

Redeemable Convertible Preferred Shares

The Company records recorded all shares of redeemable convertible preferred shares at the amount of proceeds received, less amounts allocated to redeemable convertible preferred shares tranche liability and issuance costs. The fair value of Series B-1 redeemable convertible preferred shares issued in connection with the Basecamp Bio share exchange transaction was estimated at fair value based on market-based factors similar to those used in determining the fair value of ordinary shares. Though not mandatorily redeemable, the redeemable convertible preferred shares are were recorded outside of permanent equity because in certain events considered not solely within the Company's control, such as a merger, acquisition, or sale of all or substantially all of the Company's assets (each, a "deemed liquidation event"), the redeemable convertible preferred shares may could become redeemable at the option of the holders of at least a majority of the then outstanding shares on or after April 29, 2026. The Company made an accounting policy election to recognize changes in the redemption value of redeemable convertible preferred shares immediately as they occur and adjust the carrying value of redeemable convertible preferred shares to equal it to its redemption value at the end of each reporting period. All outstanding shares of the redeemable convertible preferred shares converted into ordinary shares upon effectiveness of its IPO, the Company's IPO in 2023.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including payroll and related expenses, costs for CMOs, costs for CROs, materials, supplies, consulting costs, and the allocated portions of facility costs, such as rent, utilities, insurance, information technology costs and general support services. Research and development costs are expensed within the consolidated statements of operations and comprehensive loss as incurred.

Fair Value of Ordinary Shares

Prior to the IPO, the fair value of the Company's ordinary shares was determined by its Board of Directors with input from management and third-party valuation specialists. The Company's approach to estimate the fair value of the Company's ordinary shares is consistent with the methods outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Determining the best estimated fair value of the Company's ordinary shares requires significant judgment and management considers several factors, including the Company's stage of development, equity market conditions affecting comparable public companies, significant milestones and

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

progress of research and development efforts. Subsequent to the Company's IPO, the fair value of the Company's ordinary shares is determined based on its closing market price of the Company's ADS, which each represents three ordinary shares.

Share-Based Compensation

The Company accounts for share-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all share-based payments including share options. The fair value method requires the Company to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The

Company uses the Black-Scholes option-pricing model to estimate the fair value of options granted that are expensed on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. Option valuation models, including the Black-Scholes option-pricing model, require the input of several assumptions.

185

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

The Company has granted share options to employees of 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 China are conditioned the IPO, and the Company recognized cumulative share-based compensation expense for share options granted to liquidity events which are outside employees based in China.

In February 2023, the Company's control. 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 in the first year following the grant of certain clinical milestones as determined by the Company's compensation committee, and subject to the employees' continuous service through each vesting date. The liquidity events are achievement of performance milestones was not probable until consummated and employees as of China cannot benefit from their share options. December 31, 2023. As such, no share-based compensation expense has been was recognized for the employees of China's performance share options during the years year ended December 31, 2022 and 2021. December 31, 2023.

Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the consolidated financial statement and tax bases of assets and liabilities at the applicable enacted tax rates. The Company will establish a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before the Company is able to realize its benefits or that future deductibility is uncertain.

The Company recognizes the tax benefit from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax position is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company recognizes interest and penalties related to income tax matters in its provision for income taxes. There were no uncertain income tax positions or As of December 31, 2023 and 2022, the unrecognized income tax benefits as of December 31, 2022 were \$0.9 million and 2021. \$0.3 million, respectively.

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 and less any excess of the fair value of the consideration paid over the carrying value of noncontrolling interest. shares. Diluted net loss per share is computed by dividing the net loss attributable to ordinary shareholders by the weighted-average weighted-

184

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. Other comprehensive loss income (loss) represents unrealized gains or losses on short-term investments that are reported as a component of shareholders' deficit equity (deficit) on the consolidated balance sheets.

JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised

186

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has 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 the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In December 2019, June 2016, the Financial Accounting Standards Board ("FASB") issued Account Standards Update ("ASU") No. 2019-12, 2016-13, *Income Taxes Financial Instruments—Credit Losses (Topic 740)—Simplifying the Accounting for Income Taxes* 326): *Measurement of Credit Losses on Financial Instruments*, which simplify various aspects 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 accounting for income taxes. This ASU removes exceptions to amortized cost basis of the general principles securities. These changes will result in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the earlier recognition of deferred tax liabilities for outside basis differences. For the Company, the credit losses. The amendments in this ASU are effective for the year ended December 31, 2022. Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The adoption Company adopted ASU 2016-13 as of this ASU January 1, 2023 and the adoption did not have a material effect impact on the Company's consolidated financial statements and related disclosures.

Accounting Pronouncements Not Yet Adopted

In June 2016, December 2023, the FASB issued ASU No. 2016-13, 2023-09, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* *Improvements to Income Tax Disclosures*, 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 requires greater disaggregation of information about a reporting entity's effective tax rate reconciliation as well

[Table of Contents](#)

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

as information on income taxes paid. This ASU applies to all entities subject to income taxes and is intended to help investors better understand an expected loss model. It also eliminates the concept of other-than-temporary impairment entity's exposure to potential changes in jurisdictional tax legislation 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 assess income tax information that affects cash flow forecasts and capital allocation decisions. This ASU is effective for the Company for fiscal years annual periods beginning after December 15, 2022 December 15, 2024, including interim periods within those fiscal years, with early adoption permitted. This ASU should be applied on a prospective basis although retrospective application is permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements and related disclosures

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The amendments in this ASU require disclosures, on an annual and interim basis, of significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"), as well as the aggregate amount of other segment items included in the reported measure of segment profit or loss. This ASU requires that a public entity disclose the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. Public entities will be required to provide all annual disclosures currently required by Topic 280 in interim periods, and entities with a single reportable segment are required to provide all the disclosures required by the amendments in this ASU and existing segment disclosures in Topic 280. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures, and does not expect the standard will have a material impact on the Company's consolidated financial statements and related disclosures.

3.Composition 3. Composition of Certain Consolidated Financial Statement Line Items

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

	DECEMBER 31,		DECEMBER 31,	
	2022	2021	2023	2022
Laboratory equipment	\$ 1,098	\$ 1,015	\$1,960	\$1,098
Furniture and fixtures	115	90	243	115
Computer equipment and software	58	42	309	58
Leasehold improvements	109	110	1,360	109
	\$ 1,380	\$ 1,257	\$3,872	\$1,380
Less: Accumulated depreciation	(349)	(72)	(644)	(349)
Property and equipment, net	\$ 1,031	\$ 1,185	\$3,228	\$1,031

[Table of Contents](#)

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

Depreciation expense for the years ended December 31, 2022 and 2021 was \$0.3 million and \$0.1 million, respectively.

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

	DECEMBER 31,		DECEMBER 31,	
	2022	2021	2023	2022
Accrued compensation	\$ 3,544	\$ 1,943	\$ 4,325	\$3,544
Accrued research and development expenses	1,818	2,053	4,719	1,818
Accrued clinical expenses	438	368	5,412	438
Accrued professional services	313	159	2,633	313
Income tax and VAT payable	174	231	356	174
Accrued other liabilities	454	71	1,113	454
Total accrued expenses and other current liabilities	\$ 6,741	\$ 4,825	\$18,558	\$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 level 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, 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, 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.

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.

[Table of Contents](#)

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

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

	DECEMBER 31,								DECEMBER 31,							
	2022				2021				2023				2022			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Money market funds	\$18,994	\$ —	\$ —	\$18,994	\$89,795	\$ —	\$ —	\$89,795	\$124,443	\$ —	\$ —	\$124,443	\$18,994	\$ —	\$ —	\$18,994
Cash equivalents	18,994	—	—	18,994	89,795	—	—	89,795	124,443	—	—	124,443	18,994	—	—	18,994
U.S. government bonds	11,763	—	—	11,763	—	—	—	—	84,935	—	—	84,935	11,763	—	—	11,763
U.S. government agency bonds	—	1,794	—	1,794	—	—	—	—	—	82,340	—	82,340	—	1,794	—	1,794
Corporate debt securities	—	51,193	—	51,193	—	2,002	—	2,002	—	170,256	—	170,256	—	51,193	—	51,193
Short-term investments	11,763	52,987	—	64,750	—	2,002	—	2,002	84,935	252,596	—	337,531	11,763	52,987	—	64,750
Total fair value of financial assets	\$30,757	\$52,987	\$ —	\$83,744	\$89,795	\$ 2,002	\$ —	\$91,797	\$209,378	\$252,596	\$ —	\$461,974	\$ 30,757	\$52,987	\$ —	\$83,744

	DECEMBER 31,								DECEMBER 31,							
	2022				2021				2023				2022			
	AMORTIZED COST	UNREALIZED LOSSES	UNREALIZED GAINS	FAIR VALUE	AMORTIZED COST	UNREALIZED LOSSES	UNREALIZED GAINS	FAIR VALUE	AMORTIZED COST	UNREALIZED LOSSES	UNREALIZED GAINS	FAIR VALUE	AMORTIZED COST	UNREALIZED LOSSES	UNREALIZED GAINS	FAIR VALUE
Money market funds	\$ 18,994	\$ —	\$ —	\$18,994	\$ 89,795	\$ —	\$ —	\$89,795	\$ 124,443	\$ —	\$ —	\$124,443	\$ 18,994	\$ —	\$ —	\$18,994
Cash equivalents	18,994	—	—	18,994	89,795	—	—	89,795	124,443	—	—	124,443	18,994	—	—	18,994
U.S. government bonds	11,820	(57)	—	11,763	—	—	—	—	84,783	(35)	187	84,935	11,820	(57)	—	11,763
U.S. government agency bonds	1,801	(7)	—	1,794	—	—	—	—	82,185	(16)	171	82,340	1,801	(7)	—	1,794
Corporate debt securities	51,239	(49)	3	51,193	2,002	—	—	2,002	170,042	(39)	253	170,256	51,239	(49)	3	51,193
Short-term investments	64,860	(113)	3	64,750	2,002	—	—	2,002	337,010	(90)	611	337,531	64,860	(113)	3	64,750

Total fair value of financial assets	\$	83,854	\$	(113)	\$	3	\$83,744	\$	91,797	\$	—	\$	—	\$91,797	\$	461,453	\$	(90)	\$	611	\$461,974	\$	83,854	\$	(113)	\$
--------------------------------------	----	--------	----	-------	----	---	----------	----	--------	----	---	----	---	----------	----	---------	----	------	----	-----	-----------	----	--------	----	-------	----

As of **December 31, 2022** **December 31, 2023** and **2021, 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 years ended **December 31, 2022** **December 31, 2023** and **2021, 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 at either **December 31, 2023** or **2022**, and no impairment losses were recognized for the years ended **December 31, 2023** and **2022**.

188

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Money market funds and U.S. government bonds are included within Level 1 of the fair value hierarchy because they are valued using quoted market prices. Corporate debt securities and U.S. government agency bonds are classified within Level 2 of the fair value hierarchy as they take into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. These inputs include reported trades of and broker/dealer quotes on similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

5. Term Loan

On August 4, 2020, the Company entered into a Loan and Security Agreement (the "SVB Agreement") with Silicon Valley Bank ("SVB") to raise for up to \$8.0 million in debt financing (the "SVB Loan") consisting of \$5.0 million available to draw on or before July 31, 2021 ("Tranche A"), and the option to draw up to an additional \$3.0 million ("Tranche B") on or before January 31, 2022, which were conditioned to initiation of a

189

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Phase 1 clinical trial on or before July 31, 2021, and nomination of a development candidate for a second asset on or prior to January 31, 2022, both of which the Company accomplished in May 2021. The Tranche B draw period was extended to July 31, 2022, upon the receipt of net cash proceeds in an amount of at least \$50.0 million from the issuance and sale by the Company of its equity securities to investors and/or subordinated debt on or prior to January 31, 2022, which the Company accomplished in July 2021. 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 connection with the entering into the SVB Agreement, the Company issued SVB a warrant to purchase **shares 112,279** of its ordinary shares at an exercise price of \$0.48 per share ("SVB Warrant"). **The Amounts available to be borrowed under the SVB Warrant is immediately exercisable for 112,279 ordinary shares of Agreement expired unused and in February 2023**, 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 and 22,283 ordinary shares upon draw of Tranche B**. 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 **issued 106,060 ordinary shares through a cashless exercise**. **exercise upon the exercise of the SVB Warrant.**

6. Commitments and Contingencies

Operating Leases

In **January 2020, June 2021, Shanghai ShouTi Shanghai** entered into **a lease an** agreement to lease approximately **6,000 5,900** square feet of office space in Chamtime Plaza in Shanghai, China. The lease commenced on **November 1, 2020, September 16, 2021** and **was scheduled to expire expired on December 31, 2022 September 15, 2023**. Shanghai ShouTi **Shanghai** had an option to extend the lease term, however the renewal term and conditions **were to should** be agreed **to** between **Shanghai ShouTi Shanghai** and the landlord. For accounting purposes, the lease term did not include the option to extend the lease term as it was not reasonably certain that the lease term would be extended. **In connection with entering into new lease agreement in Chamtime Plaza in June 2021, the lease agreement was terminated early on October 31, 2021.**

In June 2021, ShouTi Shanghai entered into a lease agreement to lease approximately 5,900 square feet of office space in Chamtime Plaza in Shanghai, China. The lease commenced on September 16, 2021 and expires on September 15, 2023. ShouTi Shanghai has an option to extend the lease term, however the renewal term and conditions should be agreed between ShouTi Shanghai and the landlord. For accounting purposes, the lease term did not include the option to extend the lease term as it is not reasonably certain that the lease term will be extended.

In November 2021, StructureTx US entered into **a lease an** agreement to lease approximately 4,050 square feet of office spaces in South San Francisco, California. The lease commenced on November 11, 2021, and **expires expired** on October 31, 2023.

In June 2023, Shanghai ShouTi entered into a lease agreement for approximately 22,500 square feet of office space in Shanghai, China, for its research and development operations office, which commenced in July 2023 and will expire on December 31, 2026. The annual base rent is approximately \$0.7 million based on the exchange rate upon entering into this lease agreement, and Shanghai ShouTi is also responsible for the payment of additional costs and fees related to its use of the premises.

According to the lease agreement, the Company is obligated to restore the premises and all fixtures, fittings and equipment in the premises to its original condition. The Company's asset retirement obligations are primarily associated with leasehold improvements which the Company is contractually obligated to remove at the end of a lease to comply with the lease agreement. The Company recognized an asset retirement obligation at the inception of a lease at its estimated fair value based on the expected timing of payment of the related costs. In the determination of fair value for an asset retirement obligation, the Company uses various assumptions and judgments, including such factors as the existence of a legal obligation, estimated amounts and timing of settlements, discount and inflation rates. The key estimates as of the inception date were the fair value of the asset retirement obligation of \$0.4 million, timing of the settlement of 3.4 years and the discount rate of 6.8%. The associated estimated asset retirement costs are capitalized as part of the carrying amount of the leasehold improvements and depreciated over its useful life. As of December 31, 2023

190189

[Table of Contents](#)

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

and 2022, the Company had asset retirement obligations of \$0.3 million and \$0, respectively, which are recorded in other non-current liabilities on the consolidated balance sheets.

In June 2023, StructureTx US 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 lease commenced in July 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 StructureTx US will also be responsible for the payment of additional costs and fees related to its use 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 lease commenced in December 2023 and will expire on January 31, 2027. The annual base rent will be approximately \$0.3 million based on the exchange rate upon entering into this lease agreement, and Shanghai ShouTi is also responsible for the payment of additional costs and fees related to its use of the premises.

The maturities of operating lease liabilities as of **December 31, 2022** **December 31, 2023**, were as follows (in thousands):

	DECEMBER 31, 2022	DECEMBER 31, 2023
2023	\$ 267	
2024		\$ 1,801
2025		2,002
2026		1,954
2027		384
Total undiscounted lease payments	267	6,141
Less: imputed interest	7	688
Total operating lease liability	260	5,453
Less: current portion	260	1,440
Operating lease liability, net of current portion	\$ —	\$ 4,013

Operating lease **cost** expense was **\$1.1** \$1.8 million and **\$0.5 million** \$1.1 million for the years ended **December 31, 2022** **December 31, 2023** and **2021, 2022**, respectively, including **\$0.7 million** \$0.9 million and **\$0.2 million** \$0.7 million short-term lease costs for the years ended **December 31, 2022** **December 31, 2023** and **2021, 2022**, respectively. As of **December 31, 2022** **December 31, 2023**, the weighted average remaining lease term was **0.8** 3.2 years, and the weighted average discount rate used to measure the lease liabilities for such operating leases upon recognition was **7.8%** 7.5%. During the years ended **December 31, 2022** **December 31, 2023** and **2021, 2022**, cash paid for amounts included in operating lease liabilities of **\$0.4** \$0.6 million and **\$0.2 million** \$0.4 million, respectively, was included in **cash flows from** operating activities on the consolidated statements of cash flows.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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 **December 31, 2022**, **December 31, 2023** and **2021, 2022**, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently had not **recorded** **recognized** any 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.

7. 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 **are** **were** issuable in series. **The Company's board**

As of **directors is authorized to determine the rights, preferences, privileges and terms of each series.**

191

Table of Contents

STRUCTURE THERAPEUTICS INC.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

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

SERIES	DECEMBER 31, 2022				
	SHARES ISSUED				
	SHARES AUTHORIZED	ORIGINAL ISSUE PRICE	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
	<u>67,018,087</u>		<u>67,018,087</u>	<u>\$ 199,975</u>	<u>\$ 198,016</u>

SERIES	DECEMBER 31, 2021				
	SHARES ISSUED				
	SHARES AUTHORIZED	ORIGINAL ISSUE PRICE	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	24,701,732	4.0483	24,701,732	100,000	100,000
B-1	2,161,402	3.2386	2,161,402	8,959	7,000
	<u>58,862,815</u>		<u>58,862,815</u>	<u>\$ 166,960</u>	<u>\$ 165,001</u>

The original issuance price in the table above reflects the stated issuance price per the respective purchase agreements.

Series A Redeemable Convertible Preferred Shares

In April 2019, the Company entered into a Series A Dividends on redeemable convertible preferred shares purchase agreement with certain investors to issue are noncumulative and sell 9,600,000 shares of its Series A redeemable convertible preferred shares at a price of \$1.6667 per share (the "Series A Purchase Price") for total gross proceeds of \$16.0 million. The issuance costs none were \$0.3 million.

The purchase agreement also provided for the issuance and sale to investors of an additional 9,600,000 Series A redeemable convertible preferred shares at the Series A Purchase Price upon achieving certain operational milestones (the "Milestone Closing") around the selection of targeted programs and progress of certain candidate programs.

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 Milestone Closing liability ("redeemable convertible preferred shares tranche liability"). During the year ended December 31, 2019, the carrying value of the redeemable convertible preferred shares was adjusted to equal to its redemption value.

The Milestone Closing occurred on December 9, 2019, and the Company issued 9,600,000 Series A redeemable convertible preferred shares at \$1.6667 per share for gross proceeds of \$16.0 million. The redeemable convertible preferred shares tranche liability was settled upon the Milestone Closing.

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC. NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Series A+ Redeemable Convertible Preferred Shares

In March 2020, the Company entered into a Series A+ redeemable convertible preferred shares purchase agreement with certain investors to issue and sell 12,799,681 shares of its Series A+ redeemable convertible preferred shares at a price of \$2.0313 per share (the "Series A+ Purchase Price") for total gross proceeds of \$26.0 million. The issuance costs were \$0.2 million.

The issuance of Series A+ redeemable convertible preferred shares was recorded at the amount of proceeds received less issuance costs. During the year ended December 31, 2020, the carrying value of the redeemable convertible preferred shares was adjusted to equal to its redemption value.

Series B Redeemable Convertible Preferred Shares

In July 2021, the Company entered into a Series B redeemable convertible preferred shares purchase agreement with certain investors to issue and sell 24,701,732 shares of its Series B redeemable convertible preferred shares at a price of \$4.0483 per share (the "Series B Purchase Price") for total gross proceeds of \$100.0 million. The issuance costs were \$3.6 million.

The issuance of Series B redeemable convertible preferred shares was recorded at the amount of proceeds received less issuance costs. During the year ended December 31, 2022, the carrying value of the redeemable convertible preferred shares was adjusted to equal to its redemption value.

In July 2021, the Company executed letter agreements with one of the investors and its affiliates granting them the right to purchase a certain number of the Company's ordinary shares equal to the product of (i) the total number of ordinary shares of the Company being sold in the Company's first firm committed underwritten public offering of the capital stock of the Company (the "IPO"), and (ii) aggregate percentage ownership of the capital stock of the Company of the investor and its affiliates (the "IPO Participation Right"). The ordinary shares offered to the investor and its affiliates shall be offered on the same terms and price at which such ordinary shares are being offered to the public pursuant to the Company's IPO. The purchase price of ordinary shares will be the fair value at the time of purchase as it will represent the fair value of the Company's ordinary shares at the time of the IPO. IPO Participation Right has no fair value as it represents a right, not obligation, to purchase additional securities at fair value.

In April 2022, the Company issued and sold an additional 8,155,272 shares of its Series B redeemable convertible preferred shares for gross proceeds of \$33.0 million, pari-passu with the other Series B shareholders. The issuance of the additional Series B redeemable convertible preferred shares was recorded at the amount of gross proceeds received less issuance costs of \$1.5 million. During the year ended December 31, 2022, the carrying value of the redeemable convertible preferred shares was adjusted to equal to its redemption value.

Series B-1 Redeemable Convertible Preferred Shares

In December 2021, the Company entered into a share exchange agreement with other investors of Series Seed redeemable convertible preferred shares of Basecamp. The Company issued 2,161,402 Series B-1 redeemable convertible preferred shares to the other investors of Series Seed redeemable convertible preferred shares of Basecamp to acquire the 7,000,000 Series Seed redeemable convertible preferred shares of Basecamp held by the other investors. The issuance costs were \$0.1 million.

The issuance of Series B-1 redeemable convertible preferred shares was recorded at the fair value of the amount of Series B-1 redeemable convertible preferred shares. The fair value of Series B-1 redeemable convertible shares was determined by management with input from third-party valuation specialists. During

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC. NOTES TO FINANCIAL STATEMENTS (CONTINUED)

the year ended December 31, 2022, the carrying value of the redeemable convertible preferred shares was adjusted to equal to its redemption value.

Rights, Preferences and Privileges

On February 7, 2023, upon the declared through conversion. Upon closing of the Company's IPO, all outstanding redeemable convertible preferred shares automatically converted into 67,018,087 ordinary shares. Prior to the closing of the Company's IPO, the holders of redeemable convertible preferred shares had the following various rights and preferences:

Voting Rights

Each share of redeemable convertible preferred share has the same voting rights as the number of shares of ordinary shares into which it is convertible and votes together with the holders of ordinary shares as a single class.

The holders of shares of Series B redeemable convertible preferred shares shall be entitled, voting separately as a single class, to elect two directors of the Company (the "Series B Directors"). The holders of shares of Series A+ redeemable convertible preferred shares shall be entitled, voting separately as a single class, to elect two directors of the Company (the "Series A+ Directors"). The holders of shares of Series A redeemable convertible preferred shares shall be entitled, voting separately as a single class, to elect two directors of the Company (the "Series A Directors"). The holders of ordinary shares shall be entitled, voting separately as a single class, to elect two directors of the Company. The holders of ordinary shares and redeemable convertible preferred shares shall be entitled, voting together, to elect the remaining directors of the Company.

Dividends

Holders of outstanding shares of redeemable convertible preferred shares are entitled on a *pari passu* one-for-one basis to participate ratably (on an as if converted to ordinary shares basis) in the payment of any dividends when, as and if declared by the board of directors on the ordinary shares. Dividends are noncumulative, and none were declared as of December 31, 2022 and 2021.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, or deemed liquidation event, either voluntary or involuntary ("Liquidation"), the holders of Series B-1 and Series B redeemable convertible preferred shares shall be entitled to receive, prior and in

preference to any distribution of any of the assets of the Company to the holders of Series A+ and Series A redeemable convertible preferred shares and ordinary shares, an amount equal to \$3.2386 per share and \$4.0483 per share, respectively, plus all declared but unpaid dividends.

If, upon the occurrence of the Liquidation, the assets and funds thus distributed among the holders of Series B-1 and Series B redeemable convertible preferred shares shall be insufficient to permit the payment to such holders of the full amounts, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of Series B-1 and Series B redeemable convertible preferred shares in proportion to the preferential amount each such holder is otherwise entitled to receive.

After the payment to the holders of Series B-1 and Series B redeemable convertible preferred shares of the full preferential amounts specified above, the holders of Series A+ and Series A redeemable convertible preferred shares shall be entitled to receive, prior and in preference to any distribution of any of the assets of

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

the Company to the holders of ordinary shares, an amount equal to \$2.0313 per share and \$1.6667 per share, respectively, plus all declared but unpaid dividends.

If, upon the occurrence of the Liquidation, the assets and funds thus distributed among the holders of Series A+ and Series A redeemable convertible preferred shares shall be insufficient to permit the payment to such holders of the full amounts, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of Series A+ and Series A redeemable convertible preferred shares in proportion to the preferential amount each such holder is otherwise entitled to receive.

After the payment to the holders of redeemable convertible preferred shares of the full preferential amounts specified above, the remaining assets of the Company available for distribution to shareholders shall be distributed among the holders of ordinary shares and redeemable convertible preferred shares pro rata based on the number of shares held by each such holder if all shares of each such series of **therefore no** redeemable convertible preferred shares were converted to ordinary shares until such time as the aggregate amount distributed to the holders of redeemable convertible preferred shares is equal to three times the applicable original issue price per redeemable convertible preferred shares then held by them.

After the payment to the holders of ordinary shares and redeemable convertible preferred shares of the full amounts specified above, all of the remaining assets of the Company available for distribution to shareholders shall be distributed among the holders of ordinary shares pro rata based on the number of shares of ordinary shares held by each such holder.

Conversion

Each redeemable convertible preferred share is convertible, at the option of the holder, into the number of fully-paid and non-assessable ordinary shares that result from dividing the applicable original issue price per share by the applicable conversion price per share at the time of conversion. Redeemable convertible preferred shares are convertible into the Company's ordinary shares on a one-for-one basis.

Each share of redeemable convertible preferred share is convertible into ordinary shares automatically immediately upon the earlier of (i) the Company's consummation of an initial public offering of the ordinary shares on an internationally recognized stock exchange (which may include, without limitation, the Hong Kong Exchange, the New York Stock Exchange or the Nasdaq Stock Market) at a public offering price per share price that implies a market capitalization of the Company immediately prior to the offering of not less than \$400.0 million, and having an aggregate offering amount of not less than \$60.0 million (a "Qualified IPO"), or (ii) the Company's receipt of a written request for such conversion from the holders of the majority of the then outstanding redeemable convertible preferred shares on an as-converted to ordinary shares basis.

Redemption

The redeemable convertible preferred shares are recorded within mezzanine equity because they will become redeemable at the option of the shareholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control after April 29, 2026. The Company made an accounting policy election to recognize changes in the redemption value of redeemable convertible preferred shares immediately as they occur and adjust the carrying value of redeemable convertible preferred shares to equal it to its redemption value at the end of each reporting period.

8. Basecamp Bio Inc.

In March 2021, Basecamp entered into a purchase agreement with certain investors to issue and sell 9,000,000 shares of its Series Seed redeemable convertible preferred shares of Basecamp at a price of \$1.00

195

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

per share for total gross proceeds of \$9.0 million. Of the 9,000,000 shares of Series Seed redeemable convertible preferred shares, 2,000,000 shares were issued to the Company and the remaining 7,000,000 shares were issued to other existing investors of the Company. Concurrent with this financing, the Company and Basecamp entered into the License and Collaboration Agreement (the "License Agreement") in which the Company granted Basecamp a license to use its proprietary structural biology technology platform to conduct a research program to discover, research and develop novel compounds for certain selected GPCR (G protein coupled receptor) targets and the Company received 14,000,000 ordinary shares of Basecamp in exchange. The Company shall make payments to Basecamp to fund the research program specified in the License Agreement, milestone payments if and when the certain milestones are achieved by Basecamp, and royalties related to net sales. The Company and Basecamp also executed a Services Agreement under which the Company provides research and development services, business development services, management and administrative services, operational services, intellectual property services to Basecamp in consideration for fees.

Basecamp was considered a variable interest entity and the Company consolidated Basecamp as it was considered the primary beneficiary. The Series Seed redeemable convertible preferred shares of Basecamp held by other investors were classified as redeemable noncontrolling interest in temporary equity because while it was not mandatorily redeemable, in the deemed liquidation event the redeemable convertible preferred shares might become redeemable at the option of the holders of at least a majority of the then outstanding shares after March 22, 2028. Losses of Basecamp were not attributed to the redeemable noncontrolling interest as the holders of Series Seed redeemable convertible preferred shares do not have a contractual obligation to share in Basecamp's losses due to their liquidation preference right.

In December 2021, the Company acquired the 7,000,000 Series Seed redeemable convertible preferred shares of Basecamp held by the other investors in exchange for 2,161,402 shares of its Series B-1 redeemable convertible preferred shares with Basecamp becoming a wholly owned subsidiary of the Company. As the share exchange did not result in a change of control, the transaction was accounted as an equity transaction. Series B-1 redeemable convertible preferred shares were accounted for at fair value of \$9.0 million, and \$2.0 million representing the excess of the fair value over the carrying amount of noncontrolling interest on the date of share exchange of \$7.0 million was recorded in additional paid-in capital and accumulated deficit.

9. Ordinary Share Warrants

In connection with the entering into the SVB Agreement on August 4, 2020, the Company issued SVB a warrant to purchase shares of the Company's ordinary shares which were recorded at fair value within additional paid-in capital in shareholders' deficit. The SVB Warrant had a fair value of \$0.1 million as of the issuance date and was recorded as a deferred asset within other non-current assets on the consolidated balance sheets that was amortized to interest and other income (expense), net, on a straight-line basis until Tranche A and Tranche B availability end date. The SVB Warrant is equity classified as it is indexed to the Company's own shares and meets all other conditions for equity classification. The SVB Warrant is not subsequently remeasured and is immediately exercisable for 112,279 ordinary shares of the Company. In addition, the SVB Warrant could have been exercisable for an additional number of ordinary shares equal to 44,567 ordinary shares upon draw of Tranche A and 22,283 ordinary shares upon draw of Tranche B. The SVB Warrant for the 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. The SVB Warrant has an exercise price of \$0.48 per share and expires in ten years. In February 2023, SVB fully exercised the SVB Warrant for 106,060 ordinary shares through a cashless exercise. December 31, 2023.

196

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

10.8. Ordinary Shares

The As of December 31, 2023, the Company's Memorandum and Articles of Association, as amended, authorizes the Company to issue 432,981,913 500,000,000 ordinary shares and 100,000,000 undesignated shares, of which 9,812,438 shares have been designated as non-voting ordinary shares and 90,187,562 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 and September 2023, the Company's board of directors designated 7,410,518 and 2,401,920 non-voting ordinary shares, respectively, 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

191

[Table of Contents](#)

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

split, combination or other similar recapitalization with respect to the ordinary shares, at such holder's election by providing written notice to the Company.

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. (collectively referred to as "BVF"), who in the aggregate hold more than 5% of December 31, 2022 the Company's issued share capital, pursuant to which BVF 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.

On September 29, 2023, the Company entered into a share purchase agreement to issue certain shares to Purchasers, including 2,401,920 newly designated non-voting ordinary shares at a purchase price of \$12.49 per share (or the equivalent of \$37.47 per ADS) in the Private Placement which closed on October 3, 2023.

As of December 31, 2023, all outstanding non-voting ordinary shares had been converted into 9,812,438 ordinary shares.

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 the preferred shareholders. As of **December 31, 2022**, **December 31, 2023** and **2021**, **2022**, no dividends on ordinary shares had been declared by the board of directors.

The Company has the following ordinary shares reserved for future issuance (in thousands):

	DECEMBER 31,		DECEMBER 31,	
	2022	2021	2023	2022
Share options issued and outstanding			11,899	7,612
Share options available for future grant			8,192	977
Ordinary shares available for employee share purchase plan			1,000	—
Conversion of redeemable convertible preferred shares	67,018	58,863	—	67,018
Share options available for future grant	977	4,026		
Share options issued and outstanding	7,612	4,646		
Ordinary share warrants	112	135	—	112
Total ordinary shares reserved	75,719	67,670	21,091	75,719

11.9. Shareholders' Equity

2019 Equity Incentive Plan

In April 2019, the Company adopted the 2019 Equity Incentive Plan ("2019 Plan"), under which its board of directors can issue share options. **As of December 31, 2022, there were 8,916,263 shares authorized and reserved for issuance under the 2019 Plan.**

Awards granted under the 2019 Plan may be either incentive share options ("ISOs"), nonstatutory share options ("NSOs"), share appreciation rights ("SARs"), or restricted share units ("RSUs"). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees and consultants. **The Company's board of directors has the authority to determine to whom options will be granted, the number of shares, the term, and the exercise price.** The exercise price of ISOs and NSOs shall not be less than 100% of the estimated fair value of the shares on the date of grant. The exercise price of ISOs granted to an employee who, at the time of grant, owns shares representing more than 10% ("10% shareholder") of the voting power of all classes of shares of the Company shall be no less than 110% of the estimated fair value of the shares on the date of grant. The options usually have a term of 10 years (or no more than five years if granted to a 10% shareholder). Vesting conditions determined by the plan administrator may apply to share options and may include continued service, performance and/or other conditions. Generally, options and restricted share awards vest over a four-year period.

197192

[Table of Contents](#)

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

2023 Equity Incentive Plan

In January 2023, prior to the IPO closing, the Company's board of directors and shareholders approved the 2023 Equity Incentive Plan ("2023 Plan"), which became effective upon the IPO closing. The Company initially reserved 12,000,000 ordinary shares for issuance of share-based compensation awards, including ISOs, NSOs, stock appreciation rights, restricted stock units and other stock-based awards, plus shares

available for issuance under the 2019 Plan. ISOs may be granted only to Company employees (including officers and directors who are also employees). Shares options granted under the 2019 Plan that are forfeited or lapse unexercised will be available for issuance under the 2023 Plan. Once the 2023 Plan became effective, no further grants were made under the 2019 Plan.

Options under the 2023 Plan may be granted for periods of up to 10 years at exercise prices no less than the fair market value of the Company's ordinary shares on the date of grant; provided, however, that the exercise price of an ISO granted to a 10% shareholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. Vesting conditions determined by the plan administrator may apply to share options and may include continued service, performance and/or other conditions. Generally, share options vest over a four-year period.

The maximum number of ordinary shares that may be issued under the 2023 Plan as of December 31, 2023 was 20,589,597. In addition, the number of ordinary shares reserved for issuance under our 2023 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2024 through January 1, 2033, in an amount equal to 4% of the total number of ordinary shares outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of ordinary shares determined by the Company's board of directors. In January 2024, the number of ordinary shares available for issuance under the 2023 Plan was increased by 5,568,838 shares as a result of the automatic increase provision in the 2023 Plan.

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	(5,451)	5,451	7.00		
Exercised	—	(498)	1.61		
Forfeited	666	(666)	4.22		
As of December 31, 2023	<u>8,192</u>	<u>11,899</u>	3.94	8.27	117,093
Exercisable at December 31, 2023		4,602	1.42	7.36	55,995
Vested and expected to vest at December 31, 2023		11,899	3.94	8.27	117,093

	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, 2021	4,026	4,646	\$ 0.83	8.96	\$ 7,911
Granted	(4,218)	4,218	2.66		
Exercised	—	(83)	0.40		
Forfeited	1,169	(1,169)	2.35		
As of December 31, 2022	<u>977</u>	<u>7,612</u>	1.62	8.57	13,283
Exercisable at December 31, 2022		2,753	1.04	8.04	6,398
Vested and expected to vest at December 31, 2022		7,612	1.62	8.57	13,283

[Table of Contents](#)

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

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying share options and the fair value of the Company's ordinary shares for share options that were in-the-money at the end of each period. The aggregate intrinsic value of options exercised for the years ended **December 31, 2022**, **December 31, 2023** and **2021** 2022 was **\$0.2 million**, **\$3.9 million** and **less than \$0.1 million**, **\$0.2 million**, respectively.

The total fair value of options that vested during the years ended **December 31, 2022**, **December 31, 2023** and **2021** 2022 was **\$1.5**, **\$5.5 million** and **\$0.3 million**, **\$1.5 million**, respectively.

Employee Share Purchase Plan

In February 2023, the Company adopted the 2023 Employee Share Purchase Plan ("ESPP"). The Company allows eligible employees to purchase shares of the Company's ordinary shares through payroll deductions at a price equal to 85% of the lesser of the fair market value of the ordinary shares as of the first date of each offering period or the ending date of each purchase period. Each offering period is typically 24 months consisting of four purchase periods of six months. There were 1,000,000 ordinary shares initially reserved for issuance under the ESPP. The number of ordinary shares reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2024 through January 1, 2033, by the lesser of (i) 1% of the total number of our outstanding share capital on the last day of the calendar month before the date of the automatic increase; and (ii) 3,000,000 ordinary shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). In January 2024, the number of ordinary shares available for issuance under the ESPP was increased by 1,392,210 shares as a result of the automatic increase provision in the ESPP.

The offering period and purchase periods are determined by the board of directors. The first offering period for approximately 24 months was initiated during the fourth quarter of 2023 and consists of four purchase periods or approximately six months. As of December 31, 2023, 1,000,000 shares under the ESPP remain available for purchase.

Compensation expense is calculated using the fair value of the employees' purchase rights under the Black-Scholes model, which was estimated using the following weighted-average assumptions:

	YEAR ENDED DECEMBER 31, 2023
Expected term (in years)	1.2
Expected volatility	90.3 %
Risk-free interest rate	4.8 %
Expected dividend yield	0.0 %

Restricted Shares

On April 29, 2019, 5,891,064 shares of the Company's ordinary shares which were previously issued to its founders were converted to restricted ordinary shares with a vesting term of four years with 25% of the shares vesting after one year from the vesting commencement date of April 29, 2019 and the remainder ratably on a monthly basis over the following three years, provided that the shareholder continues to provide services to the Company as of the date of such vesting. The transaction was accounted for as a grant of restricted shares with weighted-average per share grant-date fair value of \$0.33 per share with the total compensation cost of \$1.9 million, which will be recognized over the **four years of four-year** requisite service period.

[Table of Contents](#)

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

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, 2021	1,513	\$ 0.33
Vested	(1,186)	0.33
Unvested, December 31, 2022	327	0.33

	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, December 31, 2023	—	—

198

[Table The fair value of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

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

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

	YEAR ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2022	2021	2023	2022
Research and development	\$ 875	\$ 946	\$3,761	\$ 875
General and administrative	1,639	541	4,430	1,639
Total share-based compensation	\$ 2,514	\$ 1,487	\$8,191	\$2,514

	YEAR ENDED DECEMBER 31,	
	2023	2022
Share options and restricted shares	\$ 8,170	\$ 2,514
ESPP	21	—
Total share-based compensation	<u>\$ 8,191</u>	<u>\$ 2,514</u>

As of **December 31, 2022** **December 31, 2023**, the total unrecognized share-based compensation expense related to unvested share options was **\$7.4** **\$31.0** million, which is expected to be recognized over the remaining weighted-average vesting period of **2.5** **3.1** years.

As of **December 31, 2022** **December 31, 2023**, the total unrecognized **share-based** compensation expense related to **unvested restricted shares** the ESPP was **\$0.1** **\$0.6** million, which is expected to be recognized over the remaining weighted-average vesting period of **0.3** **1.9** years.

The fair value of restricted shares vested during the years ended December 31, 2022 and 2021 was \$0.4 million and \$0.5 million, respectively.

The Company estimated the fair value of share options using the Black Scholes option-pricing model. The fair value of share options is being amortized on a straight-line basis over the requisite service period of the awards. The options granted during the years ended **December 31, 2022** **December 31, 2023** and **2021** **2022** had a weighted-average

195

[Table of Contents](#)

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

per share grant-date fair value of **\$1.96** **\$6.21** and **\$1.07** **\$1.96** per share, respectively, which was estimated using the following weighted-average assumptions:

	YEAR ENDED DECEMBER 31,	
	2022	2021
Expected term (in years)	5.9	5.9
Expected volatility	87.7 %	85.2 %
Risk-free interest rate	2.0 %	0.9 %
Expected dividend yield	0.0 %	0.0 %

	YEAR ENDED DECEMBER 31,	
	2023	2022
Expected term (in years)	6.1	5.9
Expected volatility	101.3 %	87.7 %
Risk-free interest rate	3.7 %	2.0 %
Expected dividend yield	0.0 %	0.0 %

The assumptions are as follows:

- *Expected term.* The expected term represents the period that the share-based awards are expected to be outstanding. The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method.

199

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.

- *Expected volatility.* The Company estimated the volatility data based on a study of publicly traded industry peer companies as it did not have any trading history for its ordinary shares. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, the Company measured historical volatility over a period equivalent to the expected term. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own share price becomes available.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.
- *Expected Dividend yield.* The expected dividend is assumed to be zero as the Company has never paid dividends and has no current plans to do so.

In addition to the assumptions used in the Black-Scholes option-pricing model, the Company recognizes the actual forfeitures by reducing the employee share-based compensation expense in the same period the forfeiture occurs.

Share Option Modification196

[Table of Contents](#)

In November 2021, the Company entered into a separation and consulting agreement in connection with the resignation of a Company founder and executive. The terms of the agreement resulted in compensation expense for unvested awards expected to vest during the consultancy of \$0.5 million was recognized immediately during the year ended December 31, 2021 as no substantive future service was required. STRUCTURE THERAPEUTICS INC.

12. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

10. Income Taxes

The following table presents loss before income tax expense (in thousands):

	YEAR ENDED		YEAR ENDED	
	DECEMBER 31,		DECEMBER 31,	
	2022	2021	2023	2022
Loss before income expense:				
Domestic loss	\$ (44,258)	\$ (35,051)	\$(79,895)	\$(44,258)

Foreign income (loss)	(7,046)	(2,767)	(9,489)	(7,046)
Loss before income tax expense	<u>\$ (51,304)</u>	<u>\$ (37,818)</u>	<u>\$ (89,384)</u>	<u>\$ (51,304)</u>

200

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

The following table presents the current and deferred income tax provision for income taxes (in thousands):

	YEAR ENDED DECEMBER 31,	
	2023	2022
Current tax provision (benefit):		
Federal	\$ —	\$ —
State	5	3
Foreign	217	74
	<u>222</u>	<u>77</u>
Deferred tax provision (benefit):		
Federal	—	—
State	—	—
Foreign	14	(60)
Total provision (benefit) for income taxes:	<u>\$ 236</u>	<u>\$ 17</u>

	YEAR ENDED DECEMBER 31,	
	2022	2021
Current tax provision (benefit):		
Federal	\$ —	\$ —
State	3	—
Foreign	74	219
	<u>77</u>	<u>219</u>
Deferred tax provision (benefit):		
Federal	—	—
State	—	—
Foreign	(60)	—
Total provision (benefit) for income taxes:	<u>\$ 17</u>	<u>\$ 219</u>

197

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

The Company is domiciled in the Cayman Islands. A reconciliation of the expected tax computed at the zero tax rate for the Cayman Islands to the total provision for income taxes was as follows:

	DECEMBER 31,	
	2022	2021
Expected tax at 0%	— %	— %
State income tax, net of federal tax	3.8	4.9
Share-based compensation	(0.6)	(0.3)
Non-deductible expenses	(0.1)	(0.2)
U.S. income tax differential	18.2	19.5
Other foreign income tax differential	0.3	2.2
Research credits	0.8	0.9
Other	0.5	(0.2)
Change in valuation allowance	(22.9)	(27.3)
Effective tax rate	— %	(0.5)%

	DECEMBER 31,	
	2023	2022
Expected tax at 0%	— %	— %
State income tax, net of federal tax	6.5	3.8
Share-based compensation	(1.9)	(0.6)
Non-deductible expenses	0.1	(0.1)
U.S. income tax differential	18.8	18.2
Other foreign income tax differential	0.8	0.3
Research credits	1.7	0.8
Other	0.4	0.5
Change in valuation allowance	(26.7)	(22.9)
Effective tax rate	(0.3)%	— %

Deferred income taxes as of each of the following periods reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

201198

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

Significant components of the Company's net deferred tax asset or liability were as follows (in thousands):

	DECEMBER 31,		DECEMBER 31,	
	2022	2021	2023	2022
Net operating loss	\$ 18,918	\$ 14,501	\$ 29,217	\$ 18,918
Research and experimentation expenses			16,911	5,986
Research credits			2,631	866
Compensation	1,336	779	1,737	1,336
Research and experimentation expenses	5,986	—		
Property and equipment	18	—		
Operating lease liability	57	146	1,030	57
Related party accrued expenses	651	1,128	1,036	651
Prepaid expenses			198	—
Property and equipment			—	18
Unrealized gains and losses			15	
Other	74	66	—	74
Research credits	866	320		
Total deferred tax assets	27,906	16,940	52,775	27,906
Valuation allowance	(27,740)	(16,797)	(51,551)	(27,740)
Net deferred tax assets	166	143	1,224	166
Right-of-use assets	(43)	(143)	(960)	(43)
Property and equipment			(110)	—
Revenue			(77)	—
Unrealized gains and losses	(63)	—	—	(63)
Other			(32)	—
Total deferred tax liabilities	(106)	(143)	(1,179)	(106)
Net deferred tax assets	\$ 60	\$ —	\$ 45	\$ 60

Realization of the Company's deferred tax assets is dependent upon the Company generating sufficient taxable income in future years to obtain benefit from the reversal of temporary differences.

Management considered all available evidence under existing tax law and anticipated expiration of tax statutes and determined that a valuation allowance of \$27.7 \$51.6 million and \$16.8 million \$27.7 million was required as of December 31, 2022 December 31, 2023 and 2021, 2022, respectively for those deferred tax assets that are not expected to provide future tax benefits.

As of December 31, 2022 December 31, 2023, the Company had available net operating loss carryforwards of \$66.4 \$84.8 million for federal income tax purposes, all of which were generated after 2017. The federal net operating loss carryforwards are not subject to expiration.

As of December 31, 2022 December 31, 2023, the net operating losses for state purposes was \$74.6 \$146.5 million and will begin to expire in 2037 if not utilized.

As of December 31, 2022 December 31, 2023, the net operating losses for Australia purposes was \$0.2 million \$3.3 million and are not subject to expiration.

As of December 31, 2022 December 31, 2023, the Company has federal and state income tax credit carryforwards, net of reserves, of \$0.6 million \$2.2 million and \$0.3 million \$0.5 million, respectively. The federal credit carryovers begin to expire in 2029 2039 and the state credit carryovers do not expire.

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

The Company has not completed a study to determine whether any ownership change per the provisions of Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions, has occurred. Utilization of the Company's net operating loss and income tax credit carryforwards may be subject to a substantial annual limitation due to ownership changes that may have occurred or that could occur in the future. These ownership changes may limit the amount of the net operating loss and income tax credit carryover that can be utilized annually to offset future taxable income. In general, an

202

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

"ownership "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding ordinary shares of a company by certain shareholders.

Uncertain Tax Positions

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company does not anticipate that there will be a substantial change in unrecognized tax benefits within the next 12 months.

The following table reconciles the change in unrecognized tax benefits for the years as follows (in thousands):

	DECEMBER 31,		DECEMBER 31,	
	2022	2021	2023	2022
Beginning of year	\$ 107	\$ —	\$289	\$107
Additions for tax positions related to current year	198	96	574	198
Additions for tax positions related to prior years	—	11	14	—
Reductions for tax positions related to prior years	(16)	—	—	(16)
End of year	\$ 289	\$ 107	\$877	\$289

The total unrecognized tax benefits do not impact the Company's effective tax rate. The Company does not anticipate that there will be a substantial change in unrecognized tax benefits within the next twelve months.

The Company recognizes interest and penalties related to unrecognized tax positions within the income tax expense line in the accompanying consolidated statements of operations and comprehensive loss. There were no accrued interest and penalties associated with uncertain tax positions as of December 31, 2022 December 31, 2023 and 2021, 2022.

The Company and its subsidiaries are subject to U.S. federal, state and foreign income tax, and in the normal course of business, its income tax returns are subject to examination by the relevant taxing authorities. As of December 31, 2022 December 31, 2023, the 2017 2018 to 2021 2022 tax years remained subject to examination in the U.S. federal tax and various state tax jurisdictions. The Company is not currently under examination by federal, state, or foreign jurisdictions.

Indefinite Reinvestment of Foreign Earnings

The Company considers the earnings of certain subsidiaries to be indefinitely invested outside the Cayman Islands on the basis of estimates that future domestic cash generation will be sufficient to meet future domestic cash needs and the specific plans for reinvestment of those

subsidiary earnings. The Company has not recorded a deferred tax liability related to the income taxes and foreign withholding taxes on indefinitely reinvested undistributed earnings of foreign subsidiaries. If the Company decides to repatriate the foreign earnings, it would need to adjust the income tax provision in the period it was determined that the earnings

200

[Table of Contents](#)

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

would no longer be indefinitely invested outside the Cayman Islands. The Company's subsidiaries in the United States do not have undistributed earnings to distribute. As of **December 31, 2022** **December 31, 2023**, a subsidiary in China has **\$0.7 million of no** undistributed **earnings which would be subject to a 10% withholding tax if distributed. earnings.**

203

[Table of Contents](#)

STRUCTURE THERAPEUTICS INC.
NOTES TO FINANCIAL STATEMENTS (CONTINUED)

On December 22, 2017 the legislation commonly known as the Tax Cuts and Jobs Act ("**TCJA**" ("**TCJA**") was signed into law. The TCJA resulted in significant changes to the treatment of research or experimental ("R&E") expenditures under Internal Revenue Code Section 174. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize all R&E expenditures that are paid or incurred in connection with their trade or business which represent costs in the experimental or laboratory sense. Specifically, costs for U.S.-based R&E activities must be amortized over five years and costs for foreign R&E activities must be amortized over 15 years; both using a midyear convention. In **2022, 2023**, the Company has capitalized **\$30.1 million** **\$58.9 million** of research and development costs. After amortization, there remains a future temporary deductible item in the amount of **\$28.5 million** **\$80.5 million**.

13, 11. 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 **share** and per share amounts):

	YEAR ENDED	
	DECEMBER 31,	
	2023	2022
Numerator:		
Net loss attributable to ordinary shareholders	\$ (89,620)	\$ (51,321)
Accretion of redeemable convertible preferred shares to their redemption value	—	(1,515)
Net loss attributable to ordinary shareholders	<u>\$ (89,620)</u>	<u>\$ (52,836)</u>
Denominator:		
Weighted-average ordinary shares outstanding	110,263	10,933
Less: weighted-average unvested restricted ordinary shares subject to repurchase	<u>(65)</u>	<u>(1,349)</u>

Weighted-average ordinary shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	110,198	9,584
Net loss per share attributable to ordinary shareholders, basic and diluted	<u>\$ (0.81)</u>	<u>\$ (5.51)</u>

	YEAR ENDED DECEMBER 31,	
	2022	2021
Numerator:		
Net loss attributable to ordinary shareholders	\$ (51,321)	\$ (38,049)
Accretion of redeemable convertible preferred shares to their redemption value	(1,515)	(3,757)
Excess of the fair value of the consideration paid over the carrying value of NCI	—	(1,959)
Net loss attributable to ordinary shareholders	<u>\$ (52,836)</u>	<u>\$ (43,765)</u>
Denominator:		
Weighted-average ordinary shares outstanding	10,933	10,889
Less: weighted-average unvested restricted ordinary shares subject to repurchase	(1,349)	(2,748)
Weighted-average ordinary shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	9,584	8,141
Net loss per share attributable to ordinary shareholders, basic and diluted	<u>\$ (5.51)</u>	<u>\$ (5.38)</u>

201

[Table of Contents](#)

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

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):

	YEAR ENDED DECEMBER 31,		DECEMBER 31,	
	2022	2021	2023	2022
Options to purchase ordinary shares			11,899	7,612
Shares committed under ESPP			106	—
Redeemable convertible preferred shares	67,018	58,863	—	67,018
Options to purchase ordinary shares	7,612	4,646		
Ordinary share warrants	112	135	—	112
Unvested restricted ordinary share awards	327	1,513	—	327
Total	<u>75,069</u>	<u>65,157</u>	<u>12,005</u>	<u>75,069</u>

204

STRUCTURE THERAPEUTICS INC.**NOTES TO FINANCIAL STATEMENTS (CONTINUED)****14. 12. Defined Contribution Plan**

The Company maintains a defined contribution plan under Section 401(k) of the Code covering substantially all full-time U.S. employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. For the year years ended December 31, 2022, December 31, 2023 and 2022, the Company started to make safe-harbor matching contributions of 100% of each dollar contributed by eligible employees, up to 4% of an employee's eligible compensation. The Company may also make discretionary contributions to the 401(k) plan. During the year years ended December 31, 2022, December 31, 2023 and 2022, matching contributions were \$0.2 million, and \$0.2 million, respectively.

15.**13. 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 years ended December 31, 2022 and 2021, the Company had existing collaboration agreements to use the results provided by Schrödinger's software platform for its research purposes. During the years ended December 31, 2022, December 31, 2023 and 2021, 2022, the Company paid \$0.2 \$0.3 million and \$0.7 \$0.2 million to Schrödinger, respectively, and had none \$0.5 million and less than \$0.1 million \$0 payable balance to Schrödinger as of December 31, 2022, December 31, 2023 and 2021, 2022, respectively.

Lhotse Collaboration Agreement with Schrödinger

In October 2020, Lhotse Bio, Inc., the Company's wholly-owned subsidiary ("Lhotse"), entered into a Collaboration Agreement (the "Lhotse-Schrödinger Agreement") with Schrödinger, which is one of the Company's shareholders, to discover and develop novel, orally bioavailable, small molecule inhibitors of lysophosphatidic acid 1 receptor ("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

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

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 December 31, 2023, the Company has paid to Schrödinger an aggregate of \$0.8 million. If Lhotse develops and commercializes a product containing a compound (a "Lhotse Collaboration Compound"), that is discovered or developed under the Lhotse-Schrödinger Agreement (a "Lhotse 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 Lhotse Collaboration Products that reach such milestones. Lhotse will also be obligated to pay Schrödinger tiered royalties on a Lhotse Collaboration Product-by-Lhotse Collaboration Product basis equal to low single digit percentages on aggregate worldwide net sales of Lhotse Collaboration Products, subject to specified reductions and offsets. Lhotse's obligation to pay royalties

to Schrödinger will expire on a Lhotse Collaboration Product-by-Lhotse 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 Lhotse Collaboration Compound contained in such Lhotse Collaboration Product in such country, (ii) the expiration of regulatory, pediatric, orphan drug, or data exclusivity with respect to such Lhotse Collaboration Product in such country, and (iii) ten years after the first commercial sale of such Lhotse Collaboration Product in such country (the "Lhotse 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 Lhotse Royalty Term) to Schrödinger continues after the expiration or termination of the Lhotse-Schrödinger Agreement. As discussed of December 31, 2023, no milestone or royalty payments have been paid or accrued.

Aconcagua Collaboration Agreement with Schrödinger

In November 2023, Aconcagua Bio, Inc., the Company's wholly-owned subsidiary ("Aconcagua"), entered into a collaboration agreement (the "Aconcagua-Schrödinger Agreement") with Schrödinger to discover and develop novel, small molecule modulators of a specific target. Under the Aconcagua-Schrödinger Agreement, Schrödinger is obligated to provide computational modeling and design support, including by using its technology platform to perform virtual screens, and Aconcagua is obligated to provide day-to-day chemistry and biology support. Pursuant to the Aconcagua-Schrödinger Agreement, a joint steering committee comprised of representatives from both parties oversees the research performed under the agreement.

During the term of the Aconcagua-Schrödinger Agreement or if longer, for a specified number of years after the effective date of the Aconcagua-Schrödinger Agreement, Schrödinger is obligated, subject to certain exceptions, to work exclusively with Aconcagua on the design, research, development and commercialization of compounds that inhibit the target. Aconcagua will solely own the research results, work product, inventions and other intellectual property generated under the Aconcagua-Schrödinger Agreement other than improvements to Schrödinger's background intellectual property.

During the term of the Aconcagua-Schrödinger Agreement, Aconcagua is obligated to pay Schrödinger a monthly active program payment in Note 8 during the year ended December 31, 2021 low six digits, which payment includes fees payable for certain Schrödinger software employed in the Collaboration, and as of December 31, 2023, existing the Company shareholders acquired has paid to Schrödinger an aggregate of \$0.3 million.

[Table of Contents](#)

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

If Aconcagua develops and commercializes a redeemable noncontrolling interest product containing a compound ("Aconcagua Collaboration Compound") that is discovered or developed under the Aconcagua-Schrödinger Agreement or a derivative thereof ("Aconcagua Collaboration Product"), Aconcagua is obligated to pay Schrödinger development, regulatory and commercialization milestone payments of up to an aggregate of \$89.0 million for the first Aconcagua Collaboration Product to achieve a particular milestone event, regardless of the number of Aconcagua Collaboration Products that reach such milestones. Aconcagua will also be obligated to pay Schrödinger tiered royalties in Basecamp the low single digit range on aggregate worldwide net sales of all Aconcagua Collaboration Products, subject to specified reductions and ultimately exchanged that interest offsets. Aconcagua's obligation to pay royalties to Schrödinger will expire on a Aconcagua Collaboration Product-by-Aconcagua Collaboration Product and country-by-country basis on the later of (i) the expiration of the last-to-expire Aconcagua owned patent claim covering the composition of matter of the Aconcagua Collaboration Compound contained in such Aconcagua Collaboration Product in such country and (ii) ten years after the first commercial sale of such Aconcagua Collaboration Product in such country ("Aconcagua Royalty Term").

Unless terminated earlier, the Aconcagua-Schrödinger Agreement will continue for Series B-1 redeemable convertible preferred three years, subject to extension by mutual written agreement of the parties. Either party may terminate the Aconcagua-Schrödinger Agreement for convenience after a specified period or for the other party's uncured material breach. Aconcagua's obligation to make milestone and royalty

payments (subject to the Aconcagua Royalty Term) to Schrödinger continues after the expiration or termination of the Aconcagua-Schrödinger Agreement, unless the Aconcagua-Schrödinger Agreement is terminated under specified circumstances. As of December 31, 2023, no milestone or royalty payments have been paid or accrued under this agreement.

Purchase of non-voting ordinary shares by BVF

In May 2023, the Company entered into an Exchange Agreement with BVF, who in the aggregate hold more than 5% of the Company's issued share capital, pursuant to which BVF delivered to the Company, a total of 7,410,518 ordinary shares of the Company.

16. Subsequent Events

In January 2023, Company, in exchange for the Company's board delivery of directors approved share options for 3,550,000 7,410,518 newly designated non-voting ordinary shares, to certain officers par value \$0.0001 per share. The exchange did not result in any change in the aggregate number of outstanding shares of the Company which were granted under as the 2023 Equity Incentive Plan exchange was implemented on February 2, 2023. The exercise a one-for-one basis.

On September 29, 2023, the Company entered into a share purchase agreement to issue certain shares to Purchasers, including 2,401,920 newly designated non-voting ordinary shares at a purchase price of \$12.49 per share (or the equivalent of these share options are equal \$37.47 per ADS) to \$5.00, which is BVF, a more than 5% shareholder of the fair market value Company, for aggregate gross proceeds of each ordinary share, based on the public offering price of \$15.00 per ADS approximately \$30.0 million, in the Company's IPO. Each share option will vest over four years, subject to the executive's continuous service through each vesting date. Of these share options granted, share options for 1,200,000 Private Placement which closed on October 3, 2023.

As of December 31, 2023, all outstanding non-voting ordinary shares are subject to achievement of certain clinical milestones in the first year following grant were converted into 9,812,438 ordinary shares.

205204

[Table of Contents](#)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023, which is the end of the period covered by this Annual Report on Form 10-K. 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 CEO Chief Executive Officer and our CFO, 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 December 31, 2022 December 31, 2023, our disclosure controls and procedures were not effective at the reasonable assurance level because level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the material weaknesses in effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2023 due to the material weakness in internal control over financial reporting, described below.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 December 31, 2022. 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

We previously identified a material weaknesses are weakness in our internal control over financial reporting that continues to exist as follows:

We of December 31, 2023 in that 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 did not result in any material misstatements to the following consolidated financial statements.

Management's Plan to Remediate the Remaining Material Weakness

We have taken and will continue to take certain measures to remediate the material weakness that continues to exist as of December 31, 2023 as efficiently and effectively as possible. We have hired additional

205

[Table of Contents](#)

accounting personnel, including but not limited to the hiring of a senior director of SEC reporting and technical accounting, senior director of financial planning and analysis, director of accounting, senior director of internal controls and senior director of accounting and controller. The material weaknesses: weakness 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.

Remediation of Previously Reported Material Weaknesses

Two material weaknesses reported in the prior year were remediated in 2023. These material weaknesses were as follows:

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.

206

[Table of Contents](#)

These material weaknesses did not result in any misstatements **To respond** to the consolidated financial statements. However, 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 ~~we~~ have taken and will continue to take certain measures to remediate the material weaknesses described above.

We have begun to hire **hired** 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 these** material weaknesses, **and including** implementation of key mitigating controls to address key **risks, risks**. We have properly segregated duties throughout our financial reporting function through hiring additional personnel and establishing key also through system changes where applicable. We designed and implemented IT general controls **over relevant IT domains** related to change management, user access and key systems relevant computer operations. The new measures have been determined 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 **have operated effectively** for a sufficient period of time and management has concluded, through testing, **to conclude** that these controls are effective. We are working to remediate the material weaknesses **previously identified have been remediated as efficiently and effectively as possible, of December 31, 2023.**

Changes in Internal Controls Over Financial Reporting

There Except for the changes in internal control as referenced above for the remediation of previously reported material weaknesses, 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 fourth quarter ended **December 31, 2022 December 31, 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

206

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.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Item 9B. Other Information.

Trading Arrangements

None. During the three months ended December 31, 2023, the following officer (as defined in Rule 16a-1(f) under the Exchange Act) adopted a "Rule 10b5-1 trading arrangement" (as such term is defined in Item 408(a) of Regulation S-K).

Type of Trading Arrangement						
Name and Position	Action	Date	Rule 10b5-1*	Non-Rule 10b5-1**	Total ADSs to be Sold	Expiration Date
Xichen Lin, Ph.D., Chief Scientific Officer	Adoption	December 28, 2023	X		106,666	December 15, 2024

* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

Not Applicable.

PART III

We will file a definitive Proxy Statement for our 2024 Annual General Meeting of shareholders (the "Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

The following table sets forth information required by this item will be set forth information regarding our directors as of the date of this Annual Report:

NAME	AGE	POSITION(S)
Daniel G. Welch ⁽¹⁾⁽²⁾⁽³⁾	65	Chairman of the Board
Raymond Stevens, Ph.D.	59	Director, Chief Executive Officer
Ramy Farid, Ph.D. ⁽²⁾	58	Director
Sharon Tetlow ⁽¹⁾⁽³⁾	63	Director
Eric Dobmeier ⁽¹⁾⁽²⁾	54	Director
Joanne Waldstreicher, M.D. ⁽³⁾	62	Director

⁽¹⁾ Member of our audit committee.

⁽²⁾ Member of our compensation committee.

⁽³⁾ Member of our nominating and governance committee.

Daniel G. Welch has served as Chairman of our board of directors since January 2022. Mr. Welch served as an Executive Partner of Sofinnova Ventures, a venture capital firm from January 2015 to February 2018. Prior to serving at Sofinnova, Mr. Welch served as Chief Executive Officer and President of InterMune, Inc., a biotechnology company, from September 2003 until its acquisition by Roche Holdings AG (OTCMKTS: RHHBY) in September 2014. Mr. Welch also served as Chairman of InterMune from May 2008 to September 2014. Prior to serving at InterMune, Mr. Welch served as Chairman and Chief Executive Officer of Triangle Pharmaceuticals, Inc., a pharmaceutical company that was acquired by Gilead Sciences, Inc. (Nasdaq: GILD) from 2002 to 2003. Prior to serving at Triangle Pharmaceuticals, Mr. Welch served as President of Biopharmaceuticals at Elan Corporation (TYO: 6099) from 2000 to 2002. Prior to serving at Elan, Mr. Welch served in various senior management roles at Sanofi-Synthelabo, now Sanofi S.A. (Nasdaq: SNY), from 1987 to 2000, including as Vice President of Worldwide Marketing and Chief Operating Officer of the U.S. business. Mr. Welch currently serves on the boards of directors of Nuvation Bio Inc. (NYSE: NUVB), SeaGen Inc. (Nasdaq: SGEN), and Ultragenyx Pharmaceutical Inc. (Nasdaq: RARE). Mr. Welch received his B.B.A. in Marketing from the University of Miami and his M.B.A. from the University of North Carolina. We believe that Mr. Welch is qualified to serve on our board of directors based on his operational and strategic expertise in the global pharmaceutical market, his experience serving on the board of directors of

[Table of Contents](#)

publicly traded pharmaceutical companies and his extensive experience in leading companies from clinical-stage drug development to large-scale global commercialization.

Raymond Stevens, Ph.D. has served as our Chief Executive Officer since May 2019 and as a member of our board of directors since February 2019. Previously, Dr. Stevens founded the Bridge Institute at the University of Southern California, where he served as Founding Director and Professor from July 2014 to May 2019, and since then as Professor Emeritus. Prior to founding the Bridge Institute, Dr. Stevens founded the iHuman Institute at ShanghaiTech University ("iHuman Institute"), in January 2012, where he has since served as Founding Director and Adjunct Professor. Prior to founding the iHuman Institute, Dr. Stevens served as Professor, Department of Integrative Structural and Computational Biology and Chemistry at The Scripps Research Institute from June 1999 to July 2014. Dr. Stevens also currently serves as a member of the board of directors of Danaher Corporation (NYSE: DHR). Dr. Stevens completed a post-doctoral fellowship in Chemistry at Harvard University. Dr. Stevens received his B.A. in Chemistry from the University of Southern Maine, and his Ph.D. in Organic Chemistry from the University of Southern California. We believe that Dr. Stevens is qualified to serve on our board of directors based on his extensive experience [Proxy Statement](#) in the [field section headed "Election of structure-based drug discovery and as a director of public and private companies. As our Chief Executive Officer, Dr. Stevens also provides invaluable insight to our management's perspective in \[Directors," "Information Regarding the board's discussions regarding our company's business and strategic plans.\]\(#\)](#)

Ramy Farid, Ph.D. has served as a member of our board of directors since April 2019. Since January 2017, Dr. Farid has served as the President and Chief Executive Officer at Schrödinger, Inc. (Nasdaq: SDGR), where he has served in various roles since 1987, including President from January 2008 to December 2016, Senior Vice President from January 2005 to December 2007, and Vice President, Scientific Development and Product Management from January 2003 to December 2004. Prior to joining Schrödinger, Dr. Farid was an Assistant Professor in the Chemistry Department at Rutgers University from July 1994 to December 2001. Dr. Farid currently serves as a member of the board of directors of Schrödinger and Ajax Therapeutics, Inc. a private biotechnology company applying computational chemistry and structure-based technologies to develop small molecules for hematologic malignancies. Dr. Farid was previously a National Institute of Health Postdoctoral Fellow in the Department of Biochemistry and Biophysics at the University of Pennsylvania. Dr. Farid received his B.S. in Chemistry from the University of Rochester and his Ph.D. in Chemistry from the California Institute of Technology. We believe that Dr. Farid is qualified to serve on our board of directors because of his extensive experience in the biopharmaceutical industry, including his expertise in drug discovery and development.

Sharon Tetlow has served as a member of our board of directors since March 2022. Since January 2016, Ms. Tetlow has served as Managing Partner of Potrero Hill Advisors, an advisory firm providing strategic and operational financial support to life sciences companies. Prior to Potrero Hill Advisors, Ms. Tetlow served as chief financial officer of several public and private biotech companies for the previous twenty years. Ms. Tetlow currently serves on the board of directors, on the nominating and governance committee and as chair of the audit committee of DICE Therapeutics, Inc. (Nasdaq: DICE), a biopharmaceutical company, on the board of directors and as chair of the audit committee of Catalyst Biosciences, Inc. (Nasdaq: CBIO), a biopharmaceutical company, and on the supervisory board and as chair of the audit committee of Valneva SE (Nasdaq: VALN, EPA: VLA), a global commercial stage, public vaccine company. Ms. Tetlow received her B.S. in Psychology from the University of Delaware and her M.B.A. from Stanford University. We believe that Ms. Tetlow is qualified to serve as a member of our board of directors because of her expertise in corporate finance and strategy in the biotechnology and pharmaceutical industries and her public company board experience.

Eric Dobmeier has served as a member of our board of directors since December 2022. Since April 2019, Mr. Dobmeier has served as President, Chief Executive Officer and a member of the Board of Directors of Chinook Therapeutics, Inc. (NASDAQ: KDNY), a publicly traded biotechnology company focused on kidney diseases. Prior to joining Chinook Therapeutics, Mr. Dobmeier served as President and Chief Executive Officer of Silverback Therapeutics, Inc. from January 2018 to June 2018. Prior to that, Mr. Dobmeier held positions of increasing responsibility at Seattle Genetics, Inc. (NASDAQ: SGEN), a publicly traded biotechnology company, from 2002 to December 2017, including as Chief Operating Officer from June 2011 to December 2017. Previously, Mr. Dobmeier was an attorney with the law firms of Venture Law Group and Heller Ehrman LLP, where he represented technology companies in connection with public and private financings, mergers and acquisitions and corporate partnering transactions. Mr. Dobmeier currently serves on the board of directors of Atara Biotherapeutics, Inc. (NASDAQ: ATRA), a publicly traded biotechnology company, where he has served since 2015. Mr. Dobmeier previously served on the boards of directors of Adaptive Biotechnologies Corp (NASDAQ: ADPT) from 2016 to

[Table of Contents](#)

2021, Stemline Therapeutics, Inc. (NASDAQ: STML) from 2012 to 2018 and Versartis from 2017 to 2018, each a publicly traded biopharmaceutical company. He received his A.B. in History from Princeton University and his J.D. from the University of California, Berkeley School of Law. We believe Mr. Dobmeier is qualified to serve as a member of our board of directors because of his legal, business development and operating experience, senior management experience at public biotechnology companies and his service as a director of other biopharmaceutical companies.

Joanne Waldstreicher, M.D., has served as a member of our board of directors since December 2022. Since December 2012, Dr. Waldstreicher has served as Chief Medical Officer at Johnson & Johnson (NYSE: JNJ), where she has served in various roles since 2002, including Chief Medical Officer & Head, Asia Pacific Medical Science at Janssen Pharmaceutical Companies of Johnson & Johnson from 2011 to 2012 and Senior Vice President, Head, Global Drug Development from 2007 to 2009. Prior to joining Johnson & Johnson, Dr. Waldstreicher oversaw endocrinology and metabolism clinical research at Merck Research Laboratories. Dr. Waldstreicher also currently serves as a faculty affiliate of the Division of Medical Ethics, Department of Population Health at New York University School of Medicine. Dr. Waldstreicher received her B.A. in Chemistry at City University of New York, Brooklyn College, and her M.D. at Harvard Medical School. We believe Dr. Waldstreicher is qualified to serve on our board of directors based on her extensive experience as a pharmaceutical executive with significant expertise in clinical development, drug development strategy and regulatory affairs.

Executive Officers

The following table sets forth information regarding our executive officers:

NAME	AGE	POSITION(S)
Raymond Stevens, Ph.D. ⁽¹⁾	59	Director, Chief Executive Officer
Jun Yoon	45	Chief Financial Officer
Xichen Lin, Ph.D.	49	Chief Scientific Officer
Mark Bach, M.D., Ph.D.	66	Chief Medical Officer
Melita Sun Jung	46	Chief Business Officer
Yingli Ma, Ph.D.	49	Chief Technology Officer

⁽¹⁾ For Dr. Stevens' biographical information, please refer to "Directors" in the preceding section.

Jun Yoon has served as our Chief Financial Officer since May 2022. He previously served as our Chief Operating Officer since February 2019. Prior to joining our company, Mr. Yoon served as Vice President, Corporate Development at Cellerant Therapeutics, Inc., a biotechnology company developing immunotherapies for hematologic malignancies and other blood-related disorders, from May 2010 to January 2016. Prior to joining Cellerant Therapeutics, Mr. Yoon served as Senior Director, Licensing & Business Development at VIA Pharmaceuticals, Inc., a biotechnology company focused on the treatment of cardiovascular disease, from August 2004 to March 2010. Previously, Mr. Yoon worked in Business Development for Syrrx, Inc., prior to its acquisition by Takeda Pharmaceutical Company Limited, from July 2000 to October 2002. Mr. Yoon currently serves as director of the GPCR Consortium, a public-private global collaboration advancing GPCR research. Mr. Yoon received his B.A. in Molecular Cell Biology from the University of California, Berkeley.

Xichen Lin, Ph.D. has served as our Chief Scientific Officer since July 2019. Prior to joining our company, Dr. Lin served as Head of External Innovation, Asia Pacific at Novo Nordisk from May 2016 to July 2019. Prior to joining Novo Nordisk A/S, Dr. Lin served as Operation Partner at C-Bridge Capital, a biotechnology investment firm, from December 2015 to May 2016. Prior to serving at C-Bridge Capital, Dr. Lin held various scientific and strategy roles at GlaxoSmithKline ("GSK"), from July 2002 to December 2015, including Head of GSK's Global Neuroinflammation Discovery Performance Unit. Dr. Lin received his B.S. in Chemistry from Peking University, and his Ph.D. in Organic Chemistry from The Pennsylvania State University.

[Table of Contents](#)

Mark Bach, M.D., Ph.D. has served as our Chief Medical Officer since June 2021. Prior to joining our company, Dr. Bach served as Senior Vice President, Endocrine Medical Sciences at Ascendis Pharma, Inc. (Nasdaq: ASND), a Danish biopharmaceutical company, from November 2020 to June 2021. Prior to serving at Ascendis Pharma, Dr. Bach served as Interim Chief Executive Officer of Accumulus Synergy, Inc., a non-profit biopharmaceutical information exchange platform, from July 2020 to October 2020. Prior to serving at Accumulus Synergy, Dr. Bach held various roles at Janssen Pharmaceuticals, Inc. from January 2010 to October 2020, including Vice President, Office of the Chief Medical Officer and Vice President

Head, Asia Pacific Medical Sciences and China Innovation. Prior to serving at Janssen, Dr. Bach held various roles at Merck & Co., Inc. (NYSE: MRK) from June 1993 to January 2010, including Vice President and Executive Director, Global Medical Organization. Dr. Bach received his B.A. in Chemistry from Carleton College, his Ph.D. in Pathology from The University of Chicago Graduate School of Biological Sciences, and his M.D. from Baylor College of Medicine.

Melita Sun Jung has served as our Chief Business Officer since May 2021. Prior to joining our company, Ms. Jung served as Senior Vice President, Head of Business Development at Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicines company, from July 2017 to May 2021. Prior to joining Sangamo Therapeutics, Ms. Jung served as Senior Director, Corporate Development at Adamas Pharmaceuticals, Inc., a biopharmaceutical company focused on neurological diseases, from July 2014 to June 2017. Prior to that, Ms. Jung served as Vice President, Business Development at Ascendancy Healthcare, Inc., a company focused on commercializing pharmaceutical products for China and other Asian markets, from April 2012 to May 2014. Prior to serving at Ascendancy Healthcare, Ms. Jung held corporate development and commercial roles for Ipsen, Ltd. (OTCMKTS: IPSEY), a biopharmaceutical company focused on oncology, rare disease and neuroscience. Previously, Ms. Jung started her career in venture capital and fund management, at Bay City Capital and Lombard Odier. Ms. Jung received her B.A. in Integrative Biology from the University of California, Berkeley.

Yingli Ma, Ph.D. has served as our Chief Technology Officer since August 2022. Previously, Dr. Ma served as General Manager and President of Basecamp Bio Inc., our wholly-owned subsidiary, from May 2021 to August 2022. Prior to joining Basecamp Bio, Dr. Ma served as General Manager of Amgen Biopharmaceutical R&D (Shanghai), the R&D site of Amgen, Inc. (Nasdaq: AMGN) in Shanghai from June 2020 to May 2021. Previously, Dr. Ma served in various roles at Amgen, including Executive Director, Structural Biology and China Research Shanghai Platforms from July 2018 to December 2019, and Principal Scientist, Structural Biology and Protein Expression from June 2014 to July 2018. Prior to serving at Amgen, Dr. Ma was Senior Scientist and Principal Scientist, Structural Chemistry Lead at GSK from April 2009 to May 2014. Dr. Ma completed her post-doctoral fellowship in Molecular Biology at Rockefeller University. Dr. Ma received her B.S. in Clinical Medicine from China Medical University, and her Ph.D. in Biochemistry and Molecular Biophysics from the University of Pennsylvania.

Family Relationships and Other Arrangements

Pursuant to our voting agreement, as amended, which terminated upon the closing of the IPO, the following directors were designated as directors to our board of directors:

- Dr. Stevens was elected by the holders of a majority of our ordinary shares.
- Dr. Waldstreicher was approved by our board of directors and elected by the holders of a majority of our Series A+ convertible preferred shares.
- Ms. Tetlow and Mr. Dobmeier were approved by our board of directors and elected by the holders of a majority of our Series A convertible preferred shares.
- Dr. Farid was designated mutually by our board of directors and approved by certain affiliated entities.

There are no family relationships among any of our executive officers and directors.

Board Composition

Our board of directors currently consists of six members, with three vacancies. In accordance with our amended and restated memorandum and articles of association, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of shareholders, the successors to the directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

[Table of Contents](#)

- The Class I directors are Ms. Tetlow and Dr. Farid, and their terms will expire at the annual meeting of shareholders to be held in 2024;
- The Class II directors are Mr. Dobmeier and Dr. Waldstreicher, and their terms will expire at the annual meeting of shareholders to be held in 2025; and
- The Class III directors are Dr. Stevens and Mr. Welch, and their terms will expire at the annual meeting of shareholders to be held in 2026.

We expect that any additional directorships resulting from an increase in the number of directors or from the filling of any current vacancies will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Under the Nasdaq Stock Market LLC Marketplace Rules (the "Nasdaq Listing Rules"), independent directors must comprise a majority of our board of directors as a public company within 12 months of listing.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based on information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors other than Raymond Stevens, Ph.D. are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Duties of Directors

Under Cayman Islands law, all of our directors owe us fiduciary duties, including a duty of loyalty, a duty to act honestly and a duty to act in good faith and in a manner they believe to be in our best interests. Our directors also have a duty to exercise the skill they actually possess and such care and diligence that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our amended and restated memorandum and articles of association, as amended and restated from time to time. We have the right to seek damages if a duty owed by any of our directors is breached.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq Listing Rules, which is available on our website at www.structuretx.com.

Audit Committee

Our audit committee consists of Sharon Tetlow, Daniel Welch and Eric Dobmeier. Our board of directors has determined that each of the members of our audit committee satisfies the Nasdaq Stock Market and SEC independence requirements. Ms. Tetlow serves as the chair of our audit committee.

The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;

[Table of Contents](#)

- reviewing, with our independent auditors and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent auditors any earnings announcements;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;

- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management are implemented;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

Our board of directors has determined that Sharon Tetlow qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Ms. Tetlow's prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Our compensation committee consists of Ramy Farid, Ph.D., Daniel Welch and Eric Dobmeier. Dr. Farid serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee satisfies the Nasdaq Stock Market independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our shareholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;

[Table of Contents](#)

- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full board of directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement (if applicable); and
- reviewing and assessing on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Daniel Welch, Sharon Tetlow "Delinquent Section 16(a) Reports," if any, and Joanne Waldstreicher, M.D. Our board of directors has determined that each of the members of this committee satisfies the Nasdaq Stock Market independence requirements. Mr. Welch serves as the chair of our nominating and governance committee. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by shareholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, and periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and assessing on an annual basis the performance of the nominating and governance committee and the nominating and governance committee charter.

We believe that the composition and functioning of our nominating and governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including liquidity risks and operational risks. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The nominating and governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors' leadership structure.

[Table of Contents](#)

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the year ended December 31, 2022, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Code of Business Conduct and Ethics and Corporate Governance Guidelines incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics which is applicable that applies to all of our officers, directors, executive officers and employees, including our principal executive officer, principal financial officer, and principal accounting officer. Our officer or controller, or persons performing similar functions. A current copy of the Code of Business Conduct and Ethics is publicly available on the Corporate Governance section of our website at www.structuretx.com. Our Code of Business Conduct and Ethics is a "code of ethics," as defined in Item 406(b) of Regulation S-K. The information contained on, or accessible from, our website is not part of this Annual Report To the extent required by reference or otherwise. We rules adopted by the SEC, we will make any legally required disclosures regarding promptly disclose future amendments to or waivers of, provisions of our Code of Business Conduct and Ethics as required by Item 5.05 or waivers of Form 8-K its requirements that apply to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions on our website.

In addition, we have adopted a set of corporate governance guidelines which reflect certain guiding principles with respect to our board's structure, procedures and committees. The guidelines are not intended to change or interpret any applicable law, rule or regulation or our amended and restated memorandum and articles of association. Our Corporate Governance Guidelines are publicly available information contained on our website at www.structuretx.com, is not considered part of, or incorporated by reference into, this Annual Report on Form 10-K or any other filing that we make with the SEC.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2022, consisting of our principal executive officer and two other most highly compensated officers serving at the end of such year, were:

- Raymond Stevens, Ph.D., our Chief Executive Officer;
- Mark Bach, M.D., Ph.D., our Chief Medical Officer; and
- Yingli Ma, Ph.D., our Chief Technology Officer.

Summary Compensation Table

The following table presents all of the compensation awarded to or earned information required by or paid to our named executive officers during the fiscal year ended December 31, 2022.

NAME AND PRINCIPAL POSITION	FISCAL YEAR	SALARY (\$)	BONUS (\$)	OPTION AWARDS (\$)(1)	NON-EQUITY INCENTIVE PLAN	ALL OTHER COMPENSATION	TOTAL (\$)
					COMPENSATION (\$)(2)	COMPENSATION (\$)	
Raymond Stevens, Ph.D. Chief Executive Officer	2022	487,333	—	—	247,500	12,500 (5)	747,333
	2021	420,000	—	377,596	283,200	—	1,080,796
Mark Bach, M.D., Ph.D. Chief Medical Officer	2022	466,375	—	—	149,499	12,500 (5)	628,374
	2021	241,288	66,000	704,928	84,206	—	1,096,422
Yingli Ma, Ph.D. Chief Technology Officer	2022	374,421 (3)	—	744,738	120,117 (4)	3,047 (6)	1,242,323

[Table of Contents](#)

(1) The amount disclosed represents the aggregate grant date fair value of the share option granted to our named executive officers during fiscal years 2022 and 2021, as applicable, under our 2019 Equity Incentive Plan, computed in accordance with FASB ASC Topic 718. This amount does not reflect the actual economic value that may this item will be realized by the named executive officer.

(2) Amounts represent the applicable named executive officer's performance bonus earned for fiscal years 2021 and 2022, as applicable, as described below under the subsection titled "—Non-Equity Incentive Plan Compensation."

(3) Dr. Ma's salary in 2022 was RMB 2,519,400. Conversion to U.S. dollars is based on the average monthly exchange rate of RMB 6.73 per U.S. dollar during fiscal year 2022.

(4) Dr. Ma's performance bonus for fiscal year 2022 was RMB 808,244. Conversion to U.S. dollars is based on the average monthly exchange rate of RMB 6.73 per U.S. dollar during fiscal year 2022.

(5) Amount represents a 401(k) match.

(6) Amount represents transportation and meal allowances paid by us on behalf of Dr. Ma. The amount paid was RMB 20,500. Conversion to U.S. dollars is based on the average monthly exchange rate of RMB 6.73 per U.S. dollar during fiscal year 2022.

Annual Base Salary

The 2022 annual base salary rates for our named executive officers are set forth in the table below.

NAME	2022 BASE
	SALARY RATE
Raymond Stevens, Ph.D. ⁽¹⁾	\$ 500,000
Mark Bach, M.D., Ph.D. ⁽²⁾	468,650
Yingli Ma, Ph.D. ⁽³⁾	376,544

(1) Dr. Stevens' annual base salary rate was effective as of March 1, 2022. Dr. Stevens' annual base salary rate was \$424,000 from January 1, 2022 until February 28, 2022.

(2) Dr. Bach's annual base salary rate was effective as of March 1, 2022. Dr. Bach's annual base salary rate was \$455,000 from January 1, 2022 until February 28, 2022.

(3) Dr. Ma's annual base salary rate of RMB 2,533,680 (USD \$376,544) was effective as of March 1, 2022. Previously, Dr. Ma's annual base salary rate was RMB 2,448,000 (USD \$363,810) from January 1, 2022 until February 28, 2022. All amounts reported herein were converted to U.S. dollars based on the average monthly exchange rate of RMB 6.73 per U.S. dollar during fiscal year 2022.

In January 2023, based upon the recommendation of our independent compensation consultant, our board of directors approved the following base salaries for each of our named executive officers, which became effective on February 2, 2023: Dr. Stevens, \$605,000; Dr. Bach, \$487,450; and Dr. Ma, RMB 2,676,930 (USD \$382,420).

Non-Equity Incentive Plan Compensation

We seek to motivate and reward our executives for achievements relative to our corporate goals and expectations for each fiscal year. In 2022, Drs. Stevens, Bach and Ma were each eligible to receive an annual performance bonus based on the achievement of certain pre-established corporate performance goals determined by our board of directors (100% weighting for Dr. Stevens and 90% weighting for Drs. Bach and Ma) and, Proxy Statement in the case of Drs. Bach sections headed "Executive Compensation" and Ma, individual performance goals (10% weighting for Drs. Bach "Information Regarding the Board and Ma). Pursuant to the terms of his executive employment agreement, Dr. Stevens' target bonus was equal to 33% of his annual base salary and could have been as high as 55% if the level of achievement exceeded expectations. Pursuant to the terms of his offer letter, Dr. Bach's target bonus was equal to 35% of his annual base salary. Pursuant to the terms of the New Ma Employment Contract (as defined below under "—Agreements With Our Named Executive Officers"), Dr. Ma's target bonus was equal to 35% of her annual base salary. In January 2023, our board of directors determined that the 2022 corporate goals were achieved at 90% overall, Dr. Stevens' target bonus was determined to be 55% and that Drs. Bach and Ma each achieved 100% of their individual performance goals. As a result, our board of directors approved 2022

annual performance bonuses for each of our named executive officers, as reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

In January 2023, based upon the recommendation of our independent compensation consultant, our board of directors approved the following target bonus amounts for each of our named executive officers, expressed as a percentage of annual base salary, which became effective on February 2, 2023: Dr. Stevens, 50%; Dr. Bach, 40%; and Dr. Ma, 40%.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our shareholders with those of our employees and consultants, including our executive officers. Our board of directors or an authorized committee thereof is responsible for approving equity grants.

We have generally used share options and restricted share awards as an incentive for long-term compensation to our executive officers because share options allow our executive officers to realize value from this form of equity compensation only if our share price increases, and restricted share awards align the interests of our executive officers with the interests of our shareholders generally. Certain share options that we have granted to our executive officers permit "early exercise, Corporate Governance," whereby the executive officer can purchase shares subject to the share option prior to vesting, subject to our right of repurchase which lapses in accordance with the vesting schedule of the share option. Similarly, ordinary shares issued pursuant to restricted share awards are subject to our right of repurchase which lapses in accordance with the vesting schedule of the restricted share award.

We may grant equity awards at such times as our board of directors determines appropriate. Our executives generally are awarded an initial grant in the form of a share option in connection with their commencement of employment with us. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

All share options are granted with an exercise price per share that is no less than the fair market value of one ordinary share on the date of grant of such award. Our share options generally vest over a four-year period. Equity awards granted to our named executive officers may be subject to acceleration of vesting and exercisability under certain termination and change in control events, as described in more detail below under the subsection titled "—Potential Payments Upon Termination or Change in Control."

On January 20, 2022, in connection with Dr. Ma's commencement of employment with us, we granted Dr. Ma a share option to purchase 400,000 ordinary shares with an exercise price of \$2.60 per share and a vesting commencement date of May 11, 2021. Dr. Ma's share option vests as follows: one-fourth of the shares subject to the share option vest on the first anniversary of the vesting commencement date, and the remaining shares vest in 36 equal monthly installments thereafter, subject to Dr. Ma's continuous service through each such vesting date.

In January 2023, based upon the recommendation of our independent compensation consultant, our board of directors approved the following share options to each of our named executive officers, which were granted under the 2023 Equity Incentive Plan (the "2023 Plan") on February 2, 2023: Dr. Stevens, 1,600,000 ordinary shares; Dr. Bach, 450,000 ordinary shares; and Dr. Ma, 250,000 ordinary shares. The exercise price per share of these share options is equal to \$5.00, which is the fair market value of each ordinary share, based on the public offering price of \$15.00 for our ADSs in our IPO. Each share option will vest over four years, subject to the executive's continuous service through each vesting date and, for Drs. Bach and Ma, subject to achievement of certain clinical milestones in the first year following grant. The options are subject to acceleration of vesting and exercisability under certain circumstances.

[Table of Contents](#)

Outstanding Equity Awards as of December 31, 2022

The following table presents the outstanding equity awards held by each named executive officer as of December 31, 2022.

OPTION AWARDS ⁽¹⁾		SHARE AWARDS ⁽¹⁾	
------------------------------	--	-----------------------------	--

Name						NUMBER OF	MARKET
		NUMBER OF	NUMBER OF			SHARES OR	VALUE OF
		SECURITIES	SECURITIES			UNITS OF	SHARES OR
		UNDERLYING	UNDERLYING	OPTION		STOCK	UNITS OF
		UNEXERCISED	UNEXERCISED	EXERCISE		THAT	STOCK THAT
	OPTIONS	OPTIONS	PRICE PER	OPTION	HAVE NOT	HAVE NOT	
	GRANT	EXERCISABLE	UNEXERCISABLE	SHARE	EXPIRATION	VESTED	VESTED
	DATE	(#)	(#)	(\$) ⁽²⁾	DATE	(#)	(\$) ⁽³⁾
Raymond Stevens, Ph.D.	4/29/2019 ⁽⁴⁾	—	—	—	—	163,641	818,205
	1/22/2020 ⁽⁵⁾	100,000	—	0.39	1/21/2030	—	—
	1/22/2021 ⁽⁶⁾	258,159	280,608	0.48	1/21/2031	—	—
Mark Bach, M.D., Ph.D.	9/23/2021 ⁽⁷⁾	218,103	363,507	1.21	9/22/2031	—	—
Yingli Ma, Ph.D.	1/20/2022 ⁽⁸⁾	158,333	241,667	2.60	1/19/2032	—	—

⁽¹⁾ All of the share option and share awards were granted under the 2019 Equity Incentive Plan (the "2019 Plan").

⁽²⁾ All of the share option awards were granted with a per share exercise price equal to the fair market value of ordinary shares on the date of grant, as determined in good faith by our board of directors or compensation committee.

⁽³⁾ The market value was computed using \$5.00 per ordinary share, based on the public offering price of \$15.00 per ADS in our IPO, in which each ADS represents three ordinary shares.

⁽⁴⁾ This restricted share award is subject to the terms of the share restriction agreement, dated April 29, 2019, with Dr. Stevens. One-fourth of the shares subject to the restricted share repurchase right vested and were released on April 29, 2020 and the remaining shares subject to the repurchase right vest and release in 36 equal monthly installments thereafter, subject to continued service through each such vesting date. In the event of a "change in control" (as defined in Dr. Stevens' share restriction agreement), the repurchase right will lapse and all of the then-unvested restricted shares subject to the repurchase right will automatically become fully vested.

⁽⁵⁾ One-fourth of the shares subject to the share option vested on May 16, 2020 and the remaining shares subject to the option vest in 36 equal monthly installments thereafter, subject to continued service through each such vesting date. The option is also subject to early exercise and is immediately exercisable as of the grant date.

⁽⁶⁾ The shares subject to the share option vest in 48 equal monthly installments, subject to continued service through each such vesting date.

⁽⁷⁾ One-fourth of the shares subject to the share option vested on June 21, 2022 and the remaining shares subject to the option vest in 36 equal monthly installments thereafter, subject to continued service through each such vesting date.

⁽⁸⁾ One-fourth of the shares subject to the share option vested on May 11, 2022 and the remaining shares subject to the option vest in 36 equal monthly installments thereafter, subject to continued service through each such vesting date.

Share options held by certain of our named executive officers are eligible for accelerated vesting under specified circumstances. See the subsection titled "—Potential Payments Upon Termination or Change in Control" below for a description of such potential acceleration.

We did not materially modify any outstanding equity awards held by our named executive officers in 2022.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company, we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Act.

Nonqualified Deferred Compensation

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Employment Arrangements With Our Named Executive Officers

Below are descriptions of our employment arrangements with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, see the subsection titled “—Potential Payments Upon Termination or Change in Control” below.

Raymond Stevens, Ph.D. We entered into an executive employment agreement with Dr. Stevens in May 2019, which governs the current terms of his employment with us. The agreement has no specific term and provides for at-will employment. Pursuant to the agreement, Dr. Stevens is entitled to an annual base salary and is eligible to receive an annual performance bonus with a target equal to a pre-determined percentage of his annual base salary, based on the achievement of certain corporate and individual objectives as determined [incorporated herein](#) by our board of directors. Dr. Stevens’ agreement also provides for certain severance benefits which will be superseded by the Severance Plan (as defined below), as described below under “—Potential Payments Upon Termination or Change in Control.” [reference.](#)

Mark Bach, M.D., Ph.D. We entered into an offer letter with Dr. Bach in April 2021, which governs the current terms of his employment with us. The agreement has no specific term and provides for at-will employment. Pursuant to the offer letter, Dr. Bach is entitled to an annual base salary and is eligible to receive an annual performance bonus with a target equal to a pre-determined percentage of his annual base salary, based on the achievement of certain corporate and individual objectives as determined by our board of directors. Dr. Bach’s offer letter also provides for certain severance benefits which will be superseded by the Severance Plan, as described below under “—Potential Payments Upon Termination or Change in Control.”

Yingli Ma, Ph.D. We entered into a new employment contract with Dr. Ma in November 2022 in connection with her appointment to serve as our Chief Technology Officer (referred to herein as the New Ma Employment Contract), which governs the current terms of her employment with us and which superseded and replaced the original employment contract we entered into with Dr. Ma in May 2021 (referred to herein as the Original Ma Employment Contract). Under the New Ma Employment Contract, Dr. Ma’s term of employment is for a fixed term, beginning on November 1, 2022 and ending on May 10, 2024. Pursuant to the New Ma Employment Contract, Dr. Ma is entitled to an annual base salary and is eligible to receive an annual performance bonus with a target equal to a pre-determined percentage of her annual base salary, based on the achievement of certain corporate and individual objectives as determined by our board of directors. In addition, on January 20, 2022, pursuant to the terms of the Original Ma Employment Contract, Dr. Ma was granted an initial share option to purchase 400,000 ordinary shares, as further described above under “—Equity-Based Incentive Awards.” The New Ma Employment Contract also provides for certain notice requirements, in accordance with applicable law.

Potential Payments Upon Termination or Change in Control

Regardless of the manner in which a named executive officer’s service terminates, each named executive officer is entitled to receive amounts earned during his or her term of service, such as unpaid salary, as applicable. In addition, Drs. Stevens and Bach are entitled to certain severance benefits under their executive employment agreement and offer letter, respectively, subject to their execution of a release of claims, return of all company property, compliance with post-termination obligations and resignation from all positions with

[Table of Contents](#)

us; such benefits will be superseded by the Severance Plan, as described below. Dr. Ma, a PRC citizen, is subject to certain notice requirements, as described below.

Employment Arrangements

Dr. Stevens’ executive employment agreement and Dr. Bach’s offer letter each provide that, if the named executive officer’s employment is terminated by us without “cause”(other than as a result of death or disability) or if the named executive officer resigns for “good reason” (each

as defined in their respective executive employment agreement or offer letter, as applicable) outside of the "change in control period" (as defined below), he will be entitled to receive (i) continued payment of his then-current base salary for six months, (ii) for Dr. Stevens only, 50% of his annual bonus target for the year in which his involuntary termination occurs, (iii) payment for the preceding calendar year's annual bonus payment if the termination or resignation occurred prior to the receipt of such preceding calendar year's annual bonus payment (any such bonus payment referred to herein as the prior year bonus), (iv) premiums for COBRA continuation health coverage for up to six months, and (v) the unvested equity awards then held by named executive officer will accelerate vesting as if he had provided an additional six months of continued services following the date of separation.

In addition, pursuant to Dr. Stevens' executive employment agreement and Dr. Bach's offer letter, in the event their employment is terminated by us without "cause" (other than as a result of death or disability) or they resign for "good reason" (each as defined in their respective executive employment agreement or offer letter, as applicable) either three months prior to or within 12 months immediately following the consummation of a change in control (such period referred to herein as the change in control period), in lieu of the severance described above, they will be entitled to receive (i) a severance payment in the amount equal to their annual base salary plus their annual bonus target for the year in which their involuntary termination occurs, (ii) their prior year bonus, if applicable, (iii) premiums for COBRA continuation health coverage for up to 12 months, and (iv) the unvested equity awards then held by the named executive officer will become fully vested and immediately exercisable.

Further, in the event of either Dr. Stevens' or Dr. Bach's termination due to death or disability, they (or their heirs or estate, as applicable) will receive (i) their target annual bonus for the year in which the separation from service occurs, prorated for the number of days elapsed in the calendar year prior to the separation from service, *plus* (ii) their prior year bonus, if applicable.

Dr. Ma is subject to certain notice requirements pursuant to the New Ma Employment Contract. In the event of Dr. Ma's resignation, she must provide at least 30 days' written notice to the company, which period may be waived by us if requested or if otherwise deemed necessary. We may terminate the New Ma Employment Contract on any ground and in any circumstance permitted by applicable law, and we will provide prior notice or pay in lieu of notice if and as required under applicable law.

Our named executive officers' share options granted prior to February 2, 2023 are subject to the terms of the 2019 Plan. Dr. Stevens' restricted shares are subject to potential vesting acceleration upon a "change in control" (as defined in Dr. Stevens' share restriction agreement evidencing his restricted shares), as described above in the Outstanding Equity Awards as of December 31, 2022 table.

Severance Plan

In January 2023, in connection with our IPO, the board of directors approved a Severance and Change in Control Plan (the "Severance Plan") pursuant to which each of our named executive officers will become eligible to receive benefits under the terms of such plan. The Severance Plan became effective on February 2, 2023 and supersedes the severance provisions in Dr. Stevens' and Dr. Bach's executive employment agreement and offer letter, respectively. The Severance Plan provides for severance and/or change in control benefits to our named executive officers upon (i) a "change in control termination" or (ii) a "regular

[Table of Contents](#)

termination" (each as described below). Upon a change in control termination, each of our named executive officers is entitled to a lump sum payment equal to a portion of their base salary (18 months for Dr. Stevens and 12 months for Drs. Bach and Ma), a lump sum payment equal to 150% (for Dr. Stevens) or 100% (for Drs. Bach and Ma) of their annual target cash bonus, payment of COBRA premiums for a period of time (up to 18 months for Dr. Stevens and 12 months for Drs. Bach and Ma) and full accelerated vesting of outstanding time-vesting equity awards. To the extent an equity award is not assumed, continued or substituted for in the event of certain change in control transactions and the executive's employment is not terminated as of immediately prior to such change in control, the vesting of such equity award will also accelerate in full (and for equity awards subject to performance vesting, performance will be deemed to be achieved at target, unless otherwise provided in individual award documents). Upon a regular termination, Dr. Stevens is entitled to a lump sum payment equal to 100% of his annual target cash bonus, and each of Drs. Stevens, Bach and Ma is entitled to a lump sum payment equal to a portion of their base salary (12 months for Dr. Stevens and nine months for Drs. Bach and Ma), payment of COBRA premiums for a period of time (up to 12 months for Dr. Stevens and nine months for Drs. Bach and Ma) and partial accelerated vesting of outstanding time-vesting equity awards (12 months for

Dr. Stevens and six months for Drs. Bach and Ma). All severance benefits under the Severance Plan are subject to the executive's execution of an effective release of claims against the company.

For purposes of the Severance Plan, a "regular termination" is an involuntary termination without "cause" (and not as a result of death or disability) or a resignation for "good reason," each as defined in the Severance Plan, in any case that does not occur during the period of time beginning three months prior to, and ending 12 months following, a "change in control", as defined in the 2023 Plan (the "change in control period"). For purposes of the Severance Plan, a "change in control termination" is an involuntary termination without cause (and not as a result of death or disability) or a resignation for good reason, in any case that occurs during the change in control period.

Other Compensation and Benefits

All of our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision and life insurance plans, in each case on the same basis as all of our other employees. We pay the premiums for the life, disability, accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

Employee Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our shareholders. In addition, we believe that our ability to grant share options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. 401(k) Plan

We maintain a 401(k) plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation up to certain Code limits, which are updated annually. For 2022, we make safe-harbor matching contributions of 100% of each dollar contributed by eligible employees, up to 4% of an employee's eligible compensation. We may also make discretionary contributions to the 401(k) plan. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not generally taxable to the employees until withdrawn or distributed from the 401(k) plan.

[Table of Contents](#)

Non-Employee Director Compensation

The following table sets forth information regarding the compensation earned or paid to our non-employee directors during the fiscal year ended December 31, 2022.

NAME	FEES EARNED OR	OPTION	TOTAL
	PAID IN CASH	AWARDS	
	(\$)	(\$)(2)(3)	(\$)
Daniel G. Welch ⁽¹⁾	224,000	2,200,215	2,424,215
Ramy Farid, Ph.D.	—	—	—
Jessica Lifton ⁽⁴⁾	—	—	—
Sharon Tetlow ⁽¹⁾	48,000	165,841	213,841
Chen Yu, M.D. ⁽⁴⁾	—	—	—
Eric Dobmeier ⁽¹⁾	1,467	217,353	218,820
Joanne Waldstreicher, M.D. ⁽¹⁾	1,467	217,353	218,820

- (1) The director is party to a board service agreement, which automatically terminated immediately upon the closing of our IPO.
- (2) The amount disclosed represents the aggregate grant date fair value of the share option granted to our non-employee directors during fiscal year 2022 under our 2019 Equity Incentive Plan, computed in accordance with FASB ASC Topic 718. This amount does not reflect the actual economic value that may be realized by the director.
- (3) As of December 31, 2022, (i) Mr. Welch held an option to purchase 1,179,122 ordinary shares, which is subject to early exercise; (ii) Ms. Tetlow held an option to purchase 80,000 ordinary shares, which is subject to early exercise; (iii) Mr. Dobmeier held an option to purchase 80,000 ordinary shares, none of which were vested as of such date; and (iv) Dr. Waldstreicher held an option to purchase 80,000 ordinary shares, none of which were vested as of such date.
- (4) Ms. Lifton and Dr. Yu each resigned from the board of directors effective February 2, 2023.

We entered into a board service agreement with Daniel G. Welch, pursuant to which, starting on January 1, 2022, Mr. Welch will be: (i) compensated \$160,000 per fiscal year for services performed as a member of the board of directors and up to \$64,000 per fiscal year to serve as the Chairman of the board of directors; and (ii) awarded a share option for 1,179,122 ordinary shares, which was granted in January 2022 under the 2019 Plan. One-third of the shares subject to the share option vested on the one-year anniversary of the vesting commencement date, with the remaining shares vesting in a series of 24 equal monthly installments, subject to his continued service through each such date.

We entered into a board service agreement with Sharon Tetlow, pursuant to which, starting on March 14, 2022, Ms. Tetlow will be: (i) compensated \$45,000 per fiscal year for services performed as a member of the board of directors and \$15,000 per fiscal year to serve as the Chair of the Audit Committee of the board of directors; and (ii) awarded a share option for 80,000 ordinary shares, which was granted in May 2022 under the 2019 Plan. One-third of the shares subject to the share option will vest on the one-year anniversary of the vesting commencement date, with the remaining shares vesting in a series of 24 equal monthly installments, subject to her continued service through each such date.

We entered into a board service agreement with Eric Dobmeier, pursuant to which, starting on December 20, 2022, Mr. Dobmeier will be: (i) compensated \$45,000 per fiscal year for services performed as a member of the board of directors; and (ii) awarded a share option for 80,000 ordinary shares, which was granted in December 2022 under the 2019 Plan. One-third of the shares subject to the share option will vest on the one-year anniversary of the vesting commencement date, with the remaining shares vesting in a series of 24 equal monthly installments, subject to his continued service through each such date.

We entered into a board service agreement with Joanne Waldstreicher, pursuant to which, starting on December 20, 2022, Dr. Waldstreicher will be: (i) compensated \$45,000 per fiscal year for services performed as a member of the board of directors; and (ii) awarded a share option for 80,000 ordinary shares, which was granted in

[Table of Contents](#)

December 2022 under the 2019 Plan. One-third of the shares subject to the share option will vest on the one-year anniversary of the vesting commencement date, with the remaining shares vesting in a series of 24 equal monthly installments, subject to her continued service through each such date.

Pursuant to their terms, the board service agreements we entered into with Mr. Welch, Ms. Tetlow, Mr. Dobmeier and Dr. Waldstreicher each automatically terminated immediately upon the closing of our IPO.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Our board of directors adopted a non-employee director compensation policy in January 2023 that became effective on February 2, 2023 and is applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors, which amounts were determined after carefully considering market data and recommendations from our independent compensation consultant:

- an annual cash retainer of \$45,000;

- an additional cash retainer of \$179,000 for service as chair of the company, in recognition of Mr. Welch's significant contributions to our board of directors;
- an additional annual cash retainer of \$7,500, \$5,000 and \$4,000 for service as a member of the audit committee, compensation committee and the nominating and governance committee, respectively;
- an additional annual cash retainer of \$15,000, \$10,000 and \$8,000 for service as chair of the audit committee, compensation committee and the nominating and governance committee, respectively;
- an initial share option to purchase 90,000 of our ordinary shares on the date of each such non-employee director's appointment to our board of directors, vesting in 36 equal monthly installments; and
- an annual share option to purchase 45,000 of our ordinary shares on the date of each of our annual shareholder meetings, vesting in 12 equal monthly installments (and will be fully vested on the day immediately preceding the next annual shareholder meeting, if sooner).

Each share option described above will be granted under our 2023 Plan. The term of each share option will be ten years, subject to earlier termination as provided in the 2023 Plan, provided that upon a termination of continuous service other than for death or "cause" (as such term is defined in the 2023 Plan), the post-termination exercise period will be 12 months from the date of termination. Each share option will vest subject to the director's continuous service with us, provided that each share option will vest in full upon a change in control of the company.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

PRINCIPAL SHAREHOLDERS

The following table sets information required by this item will be set forth as of March 15, 2023, information regarding beneficial ownership of ordinary shares by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our issued share capital;
- each of our named executive officers;
- each of our directors; and

223

[Table of Contents](#)

- all of our current executive officers and directors as a group.

The percentage ownership information is based on 114,729,529 ordinary shares outstanding as of March 15, 2023, which includes the conversion of all outstanding preferred shares into an aggregate of 67,018,087 ordinary shares in connection with the closing of the IPO and the sale of 57,053,000 ordinary shares represented by ADSs in the IPO.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security. In addition, the rules include ordinary shares issuable upon the exercise of options that are currently exercisable or exercisable within 60 days of March 15, 2023. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The information contained Proxy Statement in the following table does not necessarily indicate beneficial ownership section headed "Security Ownership of Certain Beneficial Owners and Management," and "Securities Authorized for any other purpose. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Structure Therapeutics Inc., 611 Gateway Blvd., Suite 223, South San Francisco, CA 94080.

NUMBER OF SHARES BENEFICIALLY	PERCENTAGE OF SHARES BENEFICIALLY
-------------------------------------	---

NAME OF BENEFICIAL OWNER	OWNED	OWNED
Greater than 5% Shareholders:		
Entities affiliated with Biotechnology Value Fund ⁽¹⁾	12,660,518	11.0 %
FMR LLC ⁽²⁾	9,414,556	8.2 %
Entities affiliated with Deep Track Capital, L.P. ⁽³⁾	7,940,346	6.9 %
Entities affiliated with Sequoia Capital China ⁽⁴⁾	7,989,196	7.0 %
FIL Limited ⁽⁵⁾	6,473,761	5.6 %
Entities affiliated with XX-I SHT Holdings Limited ⁽⁶⁾	6,250,674	5.4 %
Named Executive Officers and Directors:		
Raymond Stevens, Ph.D. ⁽⁷⁾	3,033,306	2.6 %
Mark Bach, M.D., Ph.D. ⁽⁸⁾	271,071	*
Yingli Ma, Ph.D. ⁽⁹⁾	200,000	*
Daniel G. Welch ⁽¹⁰⁾	1,302,630	1.1 %
Sharon Tetlow ⁽¹¹⁾	80,000	*
Ramy Farid, Ph.D. ⁽¹²⁾	4,085,495	3.6 %
Eric Dobmeier	—	—
Joanne Waldstreicher, M.D.	—	—
All current executive officers and directors as a group (11 persons) ⁽¹³⁾	12,409,113	10.5 %

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 6,819,782 ordinary shares directly held, by Biotechnology Value Fund, L.P. ("BVF1"), including 2,801,529 ordinary shares represented by 933,843 ADSs it directly owns, (ii) 5,060,317 ordinary shares held by Biotechnology Value Fund II, L.P. ("BVF2"), including 2,130,657 ordinary shares represented by 710,219 ADSs it directly owns, (iii) 704,360 ordinary shares held by Biotechnology Value Trading Fund OS, L.P. ("Trading Fund OS"), including 241,755 ordinary shares represented by 80,585 ADSs it directly owns, and (iv) 76,059 ordinary shares underlying 25,353 ADSs held in a certain account managed by BVF Partners L.P. ("BVF Partners"). BVF I GP LLC ("BVF GP"), as the general partner of BVF1, may be deemed to beneficially own the shares beneficially owned by BVF1. BVF II GP LLC ("BVF2 GP"), as the general partner of BVF2, may be deemed to beneficially own the shares beneficially owned by BVF2. BVF Partners OS Ltd. ("Partners OS"), as the general partner of Trading Fund OS, may be deemed to beneficially own the shares beneficially owned by Trading Fund OS. BVF GP Holdings LLC ("BVF GPH"), as the sole member of each of BVF GP and BVF2 GP, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF1 and BVF2. BVF Partners, as the investment manager of BVF1, BVF2, Trading Fund OS and the sole member of Partners OS, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF1, BVF2 and Trading Fund OS. BVF Inc., as the general partner of BVF Partners, may be deemed to beneficially own the shares beneficially owned by BVF Partners. Mark Lampert, as a director and officer of BVF Inc., has shared voting and dispositive power over the shares and

[Table of Contents](#)

may be deemed to beneficially own the shares owned by BVF Inc. The business address of BVF1, BVF GP, BVF2, BVF2 GP, BVF GPH, BVF Partners, BVF Inc., and Mr. Lampert is 44 Montgomery St., 40th Floor, San Francisco, California 94104. The business address of Trading Fund OS and Partners OS is PO Box 309 Ugland House, Grand Cayman, KY1 1104, Cayman Islands. The foregoing information is based on a Schedule 13G filed by BVF1, BVF GP, BVF2, BVF2 GP, BVF GPH, BVF Partners, BVF Inc., and Mr. Lampert on February 13, 2023.

(2) Consists of 9,414,556 ordinary shares beneficially owned, or which may be deemed to be owned, by FMR LLC, certain of its subsidiaries and affiliates and other companies, with sole dispositive power. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of the above entities is 245 Summer Street, Boston, MA 02210. The foregoing information is based on a Schedule 13G filed on February 10, 2023 by FMR LLC and Abigail P. Johnson.

(3) Consists of 7,940,346 ordinary shares beneficially owned by Deep Track Biotechnology Master Fund, Ltd., (the "Master Fund"). Deep Track Capital, LP, (the "Deep Track Capital") serves as the investment manager to the Master Fund and may be deemed to beneficially own such shares. Deep Track Capital GP, LLC, (the "General Partner"), is the General Partner of the Investment Manager. David Kroin is the Chief Investment Officer of the Investment Manager and managing member of the General Partner and may be deemed to have shared voting and dispositive power over such shares and beneficially own such shares. The business address of the Master Fund, the Investment Manager, the General Partner and Mr. Kroin is 200 Greenwich Avenue, 3rd Floor, Greenwich, CT 06830. The foregoing information is based on a Schedule 13G filed by the Master Fund, Deep Track Capital, LP and David Kroin on February 3, 2023.

(4) Consists of (i) 7,649,547 ordinary shares held by SCC Venture VII Holdco I, Ltd. and (ii) 339,649 ordinary shares held by SCC Seed II Holdco, Ltd. The sole shareholder of SCC Venture VII Holdco I, Ltd. is Sequoia Capital China Venture Fund VII, L.P. The general partner of Sequoia Capital China Venture Fund VII, L.P. is SC China Venture VII Management, L.P., whose general partner is SC China Holding Limited. The sole shareholder of SCC Seed II Holdco, Ltd. is Sequoia Capital China Seed Fund II, L.P. The general partner of Sequoia Capital China Seed Fund II, L.P. is SC China Seed Fund II Management, L.P., whose general partner is SC China Holding Limited. SC China Holding Limited is wholly owned by SNP China Enterprises Limited, which in turn is wholly owned by Mr. Neil Nanpeng Shen. The address for each of SCC Venture VII Holdco I, Ltd. and SCC Seed II Holdco, Ltd. is Maples Corporate Services Limited, PO Box 309, Ugland House, Grand Cayman, KY1 1104, Cayman Islands.

(5) Consists of 6,473,761 ordinary shares held by FIL Limited ("FIL") with sole voting and dispositive power. Pandanus Partners, L.P. ("Pandanus") owns shares of FIL stock. While the percentage of total voting power represented by these shares of FIL voting stock may fluctuate as a result of changes in the total number of shares of FIL voting stock outstanding from time to time, it normally represents more than 25% and less than 48.5% of the total votes which may be cast by all holders of FIL voting stock. Pandanus Associates, Inc. ("PAI") acts as general partner of Pandanus. Pandanus is owned by trusts for the benefit of members of the Johnson family, including FIL's Chairman Abigail P. Johnson, but disclaims that any such member is a beneficial owner of the securities. The ordinary shares are held by Eight Roads GP FI and Eight Roads Holdings Limited FI, subsidiaries of the reporting persons under the Schedule 13G. The address of the above entities is Pembroke Hall, 42 Crow Lane, Pembroke, Bermuda HM 19. The foregoing information is based on a Schedule 13G filed on February 10, 2023 by FIL, Pandanus and PAI.

(6) Consists of (i) 5,911,025 ordinary shares held by XX-I SHT Holdings Limited and (ii) 339,649 ordinary shares held by BSCP Holdings Limited. XX-I SHT Holdings Limited and BSCP Holdings Limited are incorporated in the Cayman Islands and are wholly owned by Hillhouse Fund IV, L.P. Hillhouse Investment Management, Ltd. ("HIM"), acts as the sole management company of Hillhouse Fund IV, L.P. HIM is deemed to be the beneficial owner of, and to control the voting power of, the shares held by XX-I SHT Holdings Limited and BSCP Holdings Limited, respectively. Mr. Lei Zhang may be deemed to have controlling power over HIM. Mr. Lei Zhang disclaims beneficial ownership of all of the shares held by XX-I SHT Holdings Limited and BSCP Holdings Limited, except to the extent of his pecuniary interest therein. The address of XX-I SHT Holdings Limited and BSCP Holdings Limited is 89 Nexus Way, Camana Bay, PO Box 31106, Grand Cayman KY1 1205, Cayman Islands.

- (7) Consists of (i) 1,075,664 ordinary shares held by Raymond Stevens, Ph.D.; (ii) 1,554,586 ordinary shares held by Raymond Stevens and Vivian Urena-Stevens, as Co-Trustees of the Stevens 2001 Revocable Trust, dated March 28, 2001 (the "Stevens Trust"); (iii) 100,000 ordinary shares Dr. Stevens has the right to acquire within 60 days of March 15, 2023 pursuant to the early exercise of a share option; and (iv) 303,056 ordinary shares Dr. Stevens has the right to acquire within 60 days of March 15, 2023 pursuant to the exercise of share options. Dr. Stevens shares voting and dispositive power with respect to the shares held by the Stevens Trust.
- (8) Consists of (i) 4,500 ordinary shares held by Dr. Bach; and (ii) 266,571 ordinary shares Dr. Bach has the right to acquire within 60 days of March 15, 2023 pursuant to the exercise of a share option.
- (9) Consists of 200,000 ordinary shares Dr. Ma has the right to acquire within 60 days of March 15, 2023 pursuant to the exercise of a share option.
- (10) Consists of (i) 123,508 ordinary shares held by Marie D. Welch Family Trust, dated June 7, 2021; and (ii) 1,179,122 ordinary shares Mr. Welch has the right to acquire within 60 days March 15, 2023 pursuant to the early exercise of a share option.
- (11) Consists of 80,000 ordinary shares Ms. Tetlow has the right to acquire within 60 days of March 15, 2023 pursuant to the early exercise of a share option.
- (12) Represents 4,085,495 ordinary shares held by Schrödinger, Inc. ("Schrödinger"). Ramy Farid Ph.D., a member of our board of directors, is the President, Chief Executive Officer and a member of the board of directors of Schrödinger and may be deemed to share voting and dispositive power over the shares held by Schrödinger. Dr. Farid disclaims beneficial ownership of the shares held by Schrödinger. The address of Schrödinger is 1540 Broadway, 24th Floor, New York, New York 10036.
- (13) Consists of (i) the shares described in note (7) through note (12) above; (ii) 1,065,464 ordinary shares held by Jun Yoon; (iii) 1,554,586 ordinary shares held by JUN SIK YOON and HAYUNG YANG YOON, Trustees of THE YOON FAMILY TRUST, dated December 11, 2019 (the "Yoon Trust"); (iv) 100,000 ordinary shares Mr. Yoon has the right to acquire within 60 days of March 15, 2023. Mr. Yoon shares voting and dispositive power with respect to the shares held by the Yoon Trust and (v) 39,583 ordinary shares Mr. Yoon has the right to acquire within 60 days of March 15, 2023 pursuant to the exercise of share options; (vi) 441,333 ordinary shares Xichen Lin, Ph.D., has the right to acquire within 60 days of March 15, 2023 pursuant to the exercise of share options; (vii) 3,000 ordinary shares held by Melita Sun Jung; and (viii) 232,645 ordinary shares Melita Sun Jung has the right to acquire within 60 days of March 15, 2023 pursuant to the exercise of share options.

[Table of Contents](#)

Securities Authorized For Issuance Under Equity Compensation Plans," and is incorporated herein by reference.

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2022:

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (\$)(b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders ⁽¹⁾	7,612,892	\$1.62	976,705
Equity compensation plans not approved by security holders	—	—	—
Total	7,612,892	\$1.62	976,705

(1) Consists of the 2019 Plan. Our board of directors adopted, and our shareholders approved, the 2023 Plan and our 2023 Employee Share Purchase Plan ("ESPP") in January 2023. The 2023 Plan and ESPP became effective on February 2, 2023. Following the effectiveness of our 2023 Plan, no further grants will be made under our 2019 Plan. Any outstanding awards granted under our 2019 Plan will remain subject to the terms of our 2019 Plan and applicable award agreements.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The following includes a summary of transactions since January 1, 2019 and any currently proposed transactions, to which we were or are to information called for by this item will be a participant, set forth in which (i) the amount involved exceeded or will exceed the lesser of \$120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years; and (ii) any of our directors, executive officers or holders of more than 5% of our issued share capital, or any affiliate or member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under Proxy Statement in the section titled "Executive headed"Transactions with Related Persons," and Director Compensation. Information Regarding the Board and Corporate Governance," and is incorporated herein by reference.

Share Exchanges

Series B-1 Convertible Preferred Share Exchange

In December 2021, we entered into a share exchange agreement with Basecamp Bio, a Cayman Islands exempted company limited by shares, and certain holders of the Basecamp Bio series seed shares (the "Basecamp Shares") pursuant to which, the holders of such shares exchanged an aggregate of 7,000,000 Basecamp Shares for 2,161,402 of our Series B-1 convertible preferred shares of the company. Each one Basecamp Share was exchanged for 0.30877158 of our Series B-1 convertible preferred shares, rounded to the nearest whole share. As a result of such share exchange, Basecamp Bio became our wholly owned subsidiary.

The table below sets forth the number of shares of our Series B-1 convertible preferred shares issued in such share exchange to our executive officers, directors, holders of more than 5% of our issued share capital and their affiliated entities or immediate family members. Each Series B-1 preferred share in the table below was

226

Table of Contents

automatically converted into and re-designated as one ordinary share immediately upon the closing of our IPO.

NAME	BASECAMP	SERIES B-1
	BIO	CONVERTIBLE
	SERIES SEED	PREFERRED
	SHARE	SHARE
	(#)	(#)
Greater than 5% shareholders:		
ERVC Healthcare V, L.P.	1,600,000	494,035
F-Prime Capital Partners Life Sciences Fund VI LP	1,500,000	463,157
SCC Seed II Holdco, Ltd.	1,100,000	339,649
BSCP Holdings Limited	1,100,000	339,649

Financings

Series A+ Convertible Preferred Share Financing

In March 2020, we entered into a Series A+ preferred share purchase agreement with various investors, pursuant to which we issued and sold an aggregate of 12,799,681 shares of our Series A+ convertible preferred shares at a price per share of \$2.0313 for gross proceeds of \$26.0 million.

The table below sets forth the number of shares of our Series A+ convertible preferred shares purchased by our executive officers, directors, holders of more than 5% of our issued share capital and their affiliated entities or immediate family members. Each Series A+ preferred share in the table below was automatically converted into and re-designated as one ordinary share immediately upon the closing of our IPO.

NAME	SERIES A+	
	CONVERTIBLE	AGGREGATE
	PREFERRED	PURCHASE
	SHARE	PRICE
	(#)	(\$)
Greater than 5% shareholders:		
ERVC Healthcare IV, L.P.	676,906	1,374,999
F-Prime Capital Partners Life Sciences Fund VI LP	676,906	1,374,999

SCC Venture VII Holdco I, Ltd.	2,461,477	4,999,998
Entities affiliated with Qiming	1,199,970	2,437,499
XX-I SHT Holdings Limited	4,922,955	9,999,999

Series B Convertible Preferred Share Financing

In a series of closings in July 2021 and April 2022, we entered into a Series B preferred share purchase agreement with various investors, pursuant to which we issued and sold an aggregate of 32,857,004 shares of our Series B convertible preferred shares at a price per share of \$4.0483 for gross proceeds of \$133.0 million.

The table below sets forth the number of shares of our Series B convertible preferred shares purchased by our executive officers, directors, holders of more than 5% of our issued share capital and their affiliated

227

Table of Contents

entities or immediate family members. Each Series B preferred share in the table below was automatically converted into and re-designated as one ordinary share immediately upon the closing of our IPO.

NAME	SERIES B	
	CONVERTIBLE	AGGREGATE
	PREFERRED SHARE	PURCHASE PRICE
	(#)	(\$)
Greater than 5% shareholders:		
ERV Healthcare IV, L.P.	494,035	2,000,002
F-Prime Capital Partners Life Sciences Fund VI LP	494,035	2,000,002
SCC Venture VII Holdco I, Ltd.	988,070	4,000,004
Entities affiliated with Qiming.	494,035	2,000,002
XX-I SHT Holdings Limited	988,070	4,000,004
Deep Track Biotechnology Master Fund, Ltd.	4,940,345	19,999,999
Entities affiliated with BVF Partners L.P.	7,410,518	30,000,000

Investors' Rights, Management, Voting and Co-Sale Agreements

In connection with our convertible preferred share financings, we entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, rights of first offer, voting rights and rights of first refusal, among other things, with certain holders of our shares. The holders of more than 5% of our issued share capital listed above are parties to these agreements. Our executive officers and directors who are parties to these agreements or who are related to parties to these agreements are Dr. Stevens, Mr. Yoon and Dr. Farid.

These shareholder agreements terminated upon the closing of our IPO, except for the registration rights granted under our investors' rights agreement, which will terminate upon the earliest of (i) the closing of a liquidation event; (ii) the fifth year anniversary of the consummation of an initial public offering; and (iii) at such time, following an initial public offering, when all registrable securities held by each shareholder can be sold without limitation and without registration in compliance with pursuant to Rule 144 of the Securities Act ("Rule 144"). As of February 7, 2023, holders of 67,018,087 of our ordinary shares ("registrable securities") or their permitted transferees or assigns are entitled to the following registration rights.

If at any time beginning on August 7, 2023, the holders of at least 50% of the registrable securities then outstanding request in writing that we effect a registration with respect to at least 20% of such registrable securities (or a lesser percentage if the anticipated aggregate price to the public from the offering is expected to exceed ten million dollars), we may be required to register their ordinary shares. We are obligated to effect at most two registrations in response to these demand registration rights.

If at any time after we become entitled under the Securities Act to register securities on a registration statement on Form S-3 (or comparable or substantially similar form), holders holding at least 20% of the registrable securities then outstanding request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least two million dollars, we will be required to file such registration statement as soon as practicable and in any event within 45 days after the date of such request; provided, however, that we will not be required to effect such a registration if, within the twelve-month period immediately preceding the date of such written request, we have already effected two registrations on Form S-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

[Table of Contents](#)

In the event that we propose to register any of our securities for cash, either for our own account or for the account of other shareholders, holders of our registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement other than with respect to certain exempt transactions, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

Ordinarily, other than selling expenses, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of our counsel; and reasonable fees and disbursements of a counsel for the selling shareholders.

Initial Public Offering Participation Rights

We entered into a letter agreement in July 2021, as amended in December 2021, with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Trading Fund OS, L.P. (collectively, "BVF"), a beneficial owner of more than 5% of our issued share capital. The letter agreement grants BVF a participation right to purchase in our IPO its pro-rata percentage of the total number of ADSs sold in our IPO as calculated immediately prior to our IPO, at the public offering price, subject to compliance with applicable securities laws. The letter agreement further provided that, under certain circumstances in which BVF is unable to participate in our IPO, we were required to offer BVF our ordinary shares through a separate private placement to be concurrent with our IPO. BVF purchased an aggregate of 1,750,000 of our ADSs in our IPO at the public offering price.

Lhotse Collaboration with Schrödinger

In October 2020, Lhotse, 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

December 31, 2022, 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 in the low single digit range on aggregate worldwide net sales of all 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 owned 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

[Table of Contents](#)

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.

Employment Arrangements and Indemnification Agreements

We have entered into employment agreements and offer letters with certain of our executive officers. For more information regarding these agreements with our executive officers, see the section titled "Executive and Director Compensation—Employment Arrangements with Our Named Executive Officers."

We have entered into indemnification agreements with certain of our current directors and executive officers, and intend to enter into new indemnification agreements with each of our current directors and executive officers. We also maintain a general liability insurance policy which covers certain liabilities of our directors and executive officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Policies and Procedures for Related Party Transactions

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds \$120,000. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than five percent of our common stock, including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or another independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;

- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and

230

Table of Contents

- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

Item 14. Principal Accounting Accountant Fees and Services.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Fees

The following information required by this item will be set forth in the Proxy Statement in the section headed "Principal Accountant Fees and Services" and is a summary incorporated by reference.

208

Table of the fees and services provided by PricewaterhouseCoopers LLP ("PwC") to the Company for the fiscal years ended December 31, 2022 and 2021. Contents

Description of Services Provided by PwC	Fiscal Year Ended	
	December 31,	
	2022	2021
Audit Fees ⁽¹⁾	\$ 1,766,000	\$ 1,210,000
Audit Related Fees	—	—
Tax Fees ⁽²⁾	—	17,000
All Other Fees ⁽³⁾	900	—
TOTAL	\$ 1,766,900	\$ 1,227,000

(1) Audit fees for 2022 were for professional services rendered for the audits of our financial statements, review of interim financial statements, assistance with registration statements filed with the SEC and services that are normally provided by the independent registered public accounting firm in connection with statutory and regulatory filings or engagements. Audit Fees for the year ended December 31, 2022, included \$930,000 incurred in connection with the filing of our Registration Statement on Form S-1 in connection with our IPO in February 2023. Audit fees for the year ended December 31, 2021 were for professional services rendered for the audit of our 2021 and 2020 financial statements, including \$20,000 incurred in connection with registration statement filings in 2022 as part of the completion of our IPO in February 2023.

- (2) Tax fees for 2021 consists of tax compliance services.
- (3) All Other Fees consists of an online accounting research tool subscription paid to PwC.

The audit committee or the chair of the audit committee pre-approves the scope of the audit, audit-related and tax services provided by our independent registered public accounting firm. The audit committee evaluates the independent registered public accounting firm's qualifications, performance and independence, and presents its conclusions to the full Board on at least an annual basis.

All of the services provided by PwC, and fees for such services, were pre-approved by the audit committee in accordance with these standards.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

- (1) FINANCIAL STATEMENTS

231

[Table of Contents](#)

Our financial statements are listed in the "Index to the Financial Statements" under Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

- (2) FINANCIAL STATEMENT SCHEDULES

All schedules to the financial statements are omitted because they are not applicable, not material or the required information is shown in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

- (3) EXHIBITS

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this Annual Report on Form 10-K, in each case as indicated therein.

232209

[Table of Contents](#)

EXHIBIT INDEX

Exhibit	Description	Form	File	Exhibit	Filing				
Number	of	No.	Date	Exhibit	Description of Document	Form	File No	Exhibit	Filing

[Table of Contents](#)

Table of Contents

10.20	Shanghai Premises Lease Contract, by and between Shanghai ShouTi Biotechnology Co., Ltd. and Shanghai	S-1	333-269200	10.25	January 12, 2023
10.21	Exchange Agreement dated May 10, 2023 between the	10-Q	001-41608	10.1	May 11, 2023
10.22	Lease Agreement, dated June 29, 2023, by and between the	8-K	001-41608	10.1	July 6, 2023
10.23	House Leasing Contract, dated June 29, 2023, by and between the Shanghai ShouTi	8-K	001-41608	10.2	July 6, 2023
10.24	Biotechnology Co., Ltd. and Sublease, dated June 29, 2023, by and between Structure	8-K	001-41608	10.3	July 6, 2023
10.25	Theranautics USA Inc. and Share Purchase Agreement, dated as of September 29,	10-Q	001-41608	10.4	November 17, 2023
10.26*	2023, by and among the Collaboration Agreement, dated November 7, 2023, by and	8-K	001-41608	10.1	November 14, 2023
16.1	between Schrödinger, Inc. and Letter from PricewaterhouseCoopers LLP	8-K	001-41608	16.1	June 5, 2023
21.1	Subsidiaries of the registrant,	S-1	333-275651	21.1	November 17, 2022
23.1	Consent of Ernst & Young LLP, Independent Registered Public				
23.2	Consent of PricewaterhouseCoopers LLP,				
24.1	Powers of Attorney (included on				
31.1^	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange				

10.20+	Board Service Agreement by and between the registrant and Joanne Waldstreicher, S				
	dated November 23, 2022.				1

10.21+	Board Service Agreement by and between the registrant and Eric Dobmeier, dated December 13, 2022.	S	1
10.22+	Non-Employee Director Compensation Policy.	S	
10.23+	Severance and Change in Control Plan.	S	
10.24*	Collaboration Agreement, by and between Lhotse Bio, Inc. and Schrödinger, LLC, dated October 9, 2020.	S	1
10.25	Shanghai Premises Lease Contract, by and between Shanghai ShouTi Biotechnology Co., Ltd. and Shanghai Changtai Business Management Co., Ltd., dated June 22, 2021.	S	1
21.1	Subsidiaries of the registrant.		
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.		
24.1	Powers of Attorney (included on the signature page).		
31.1^	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
31.2^	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
32.1^	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
32.2^	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
101.INS			